United States Court of Appeals

for the Second Circuit

APPENDIX

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NO. 74-2284 et al.

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Nos. 74-2284, 74-2286, 74-2308, 74-2450, 74-2449

JOINT APPENDIX TO THE BRIEFS

VOLUME IV

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.,

HOOKER CHEMICALS & PLASTICS CORP.,

UNION CARBIDE CORPORATION,

TENNECO CHEMICALS, INC.

and

AIR PRODUCTS AND CHEMICALS, INC.,

Petitioners,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
UNITED STATES DEPARTMENT OF LABOR;
PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR;
and JOHN H. STENDER, ASSISTANT SECRETARY
FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

On Petition For Review Of An Order Of
The Occupational Safety and Health Administration,
United States Department of Labor

UNITED STATES COURT OF APPEALS
FILED
DEC 10 1974
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SECOND CIRCUIT

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November 12, 1974

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staff for a report of their observations.

And first I would like to call on Dr. Ralph Cook who is in charge of the Midland Division's Health Inventory Program.

Dr. Cook will describe this medical surveillance program and give the results of his observations.

Dr. Cook.

STATEMENT OF RALPH COOK, M. D., MIDLAND DIVISION, DOW CHEMICAL U.S.A.

DR. COOK: My name is Dr. Ralph Cook. I am a physician at the Midland Division of Dow Chemical U.S.A.

I obtained my medical degree from Wayne State University. I received residency training in occupational medicine, and a master's degree in public health from the University of Michigan.

I have completed requirements for certification in occupational medicine, and have taken my Board examinations.

While in the military, I worked in the toxicology laboratory of the Army Environmental Hygiene Agency, Edgewood Arsenal, Maryland.

At the present time, I am involved in a study for the Division of Medical Sciences, National Research Council, under contract to the Environmental Protection Agency. I came to Dow two years ago and am currently in charge of the Division's Health Inventory Program.

Today, I would like to report an analysis of selected health surveillance data on 335 chemical workers who had industrial exposures to vinyl chloride. The details of their exposures have already been reviewed by Mr. Daniel.

In the clinical parameters considered in our study, there was nothing of statistical significance below vinyl chloride levels of 200 ppm. Above this level only diastolic blood pressure showed a statistically significant deviation.

We have provided employee periodic health examinations to a varying degree for over 20 years. I refer you to the American Industrial Hygiene Association Journal [Vol 33, pg 19 (1972)] in which C. G. Kramer and J. E. Mutchler of The Dow Chemical Company correlated clinical and environmental measurements for workers exposed to vinyl chloride prior to 1967.

Their findings "suggest that repeated exposure to vinyl chloride at TWA levels of 300 ppm or above for a working lifetime together with very low levels of vinylidene chloride may result in slight changes in certain physiological and clinical laboratory parameters.

"The possibility of some impairments in liver function tests must be considered, even though no overt clinical disease was evident in any of the individuals studied".

Since 1967, we have utilized multiphasic health screening techniques to evaluate our employees' health status. We call this our Health Inventory Program.

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The employee is evaluated in our Health Screening Center which, during the year, is moved to various locations around the plant. This program has evolved somewhat since its inception to the point where it now includes a history and the measurement of over 40 separate anthropomorphical and biochemical variables. It is an extraction of data from this program that I wish to discuss today.

A synopsis of the parameters that are evaluated by our current program is covered by Table 1 which is in the record.

The medical history includes, among other things, information on hospitalizations, numbness in the hands, respiratory difficulties, liver problems, alcohol ingestion, anemia and current medications. We do a detailed smoking history. We inquire into the number of stillborns, miscarriages, birth defects.

Our evaluation includes chest x-ray. electrocardiogram, pulmonary functions, hematology, urinalysis, and a variety of blood chemistries, including lactic dehydrogenase (LDH), serum glutamic oxalacetic transaminase (SGOT), total bilirubin, alkaline phosphatase, BUN, uric acid, creatinine, calcium, total protein, albumin, and cholesterol.

The results are compiled and reviewed by a physician. Based upon the physician's evaluation, followup studies are instituted.

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We recommend that each employee requests that we forward the results of his periodic health inventory evaluation on to his personal physician. We stress responsible followup; continuity of medical care.

In this study, the population of interest was defined to be production employees at one manufacturing location who worked for at least one year between 1942 and January 1972 in areas with potential vinyl chloride exposure.

It was further defined to include only those individuals who were employees of the Midland Division between February 1967 and March 1974, the inclusive period of the health inventory program.

Based upon a review of industrial hygiene data, each individual was assigned to one of four exposure groups -- high, intermediate, low and undefined.

The categories were based on estimated time weighted average concentrations for an eight-hour day (TWA). The high level was defined as exposures above 200 ppm for at least one month's duration; the intermediate level was 25 to 200 ppm; and the low level as less than 25 ppm.

For 81 individuals, insufficient industrial hygiene data was available to accurately estimate their exposures, and they were placed in the undefined group. A subjective evaluation by industrial hygienists indicated that the exposures in this undefined group were, for the most part, in the low to

ms-17

intermediate range.

In placement of individuals in particular exposure groups, precedence was given first to a history of high, then intermediate, next undefined and finally low exposure.

Table 2 also in the record gives a breakdown as to the number of employees in each group and the number who voluntarily participated in the Health Inventory Program. The participation rate among the various exposure groups was about 80 percent.

As of March 1974, we were in the final stages of our fourth cycle through the plant. Because of major revisions in the Health Inventory Program in 1970, data before and after this data have been analyzed separately. This conveniently breaks our analysis down into a study of the first two cycles and the last two.

In the first two cycles, February 1967 to December 1970, ten clinical parameters were evaluated. Two of them, serum protein and hemoglobin, had insufficient data and were discarded.

Data of the remaining eight were analyzed: FVC (Forced Vital Capacity), FEV_1 (Forced Expiratory Volume - One Second), systolic blood pressure, diastolic blood pressure, white blood count, total bilirubin, SGPT (Serum Glutamic Pyruvic Transminase) and alkaline phosphatase. The mean value of each of these tests was determined for the exposure group and for a control group of matched pairs.

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The control group was matched for sex, age, smoking history, month of exam, and, where possible, master number.

Our master numbers are sequential based upon date of hire. Master numbers of similar magnitude indicate similar lengths of employment.

The only statistically significant deviation ($P < .05$) was for a decreased diastolic blood pressure on the high exposure group.

All other tests in all exposure groups, including undefined exposure, showed no statistically significant differences. What's the clinical significance of this finding? I don't know.

A number of questions from the history have also been analysed -- shortness of breath, chronic cough, yellow jaundice, stomach, liver, intestinal trouble, numbness in hands and feet, cancer or malignant growth, anemia or blood problems. No significant differences were noted between the exposure and the matched pair control groups.

Similar analyses were made on selected laboratory data and questions of the last two health inventories, January 1971 to March 1974.

Tables 3 and 4 give a list of parameters that were considered for this report. The questions were similar to those asked previously.

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The laboratory studies included pulmonary functions, hemoglobin, white blood count, total bilirubin, SGOT (Serum Glutamic Oxalecetic Transaminase), LDH (lactic dehydrogenase), total protein, protein albumin, and protein globulin.

During this period, three separate techniques for alkaline phosphatase, involving three separate normal ranges, were utilized by our consulting laboratory. For this reason, statistical analysis of the results of this study was not done.

Review of the individual results revealed nothing of clinical concern. In all other parameters studied, nothing of statistical significance was found.

We have studied various parameters of our employees' health for over 20 years, including a number of those suggested by the proposed standard. We plan to continue this medical surveillance and plan to continue incorporating new techniques as they are developed and as they apply to our operation -- automated multiphasic testing, computerized medical records, enzymatic studies, analysis of metabolic end products, chromosome studies, exfoliative cytology.

This report is a summary of our findings of past studies. Above 200 ppm, some deviations were noted in various health parameters; below 200 ppm, nothing of statistical significance has been observed.

A group from the Institute of Environmental and Industrial Health, University of Michigan, has done an extensive

study of over 5,000 employees of 32 plants involved in various phases of vinyl chloride and polyvinyl chloride manufacturing. Their findings can be found in a series of articles entitled "Occupational Acroosteolysis" in the Archives of Environmental Health (Volume 22, page 61, January 1971).

Our Midland location was one of the plants studied. They found no acroosteolysis in our work force.

As has been mentioned in previous testimony, a group of health researchers from Mt. Sinai New York Medical Center has also recently studied a group of our Midland location employees.

In Dr. Selikoff's preliminary evaluation, he brings up some interesting clinical observations. Dr. Selikoff stated his evaluation is incomplete and further analysis of his data is needed.

As Dow has indicated to Dr. Selikoff several times, we look forward to working with him in developing meaningful dose response information, of combining our 20 plus years of industrial hygiene data, our 20 plus years of medical surveillance data, with his expertise in occupational medicine. Our ultimate concern is the health of our employees.

MR. ROWE: Next I would like to call on Dr. Ben Holder, Medical Director of the Midland Division, who will discuss the results of a study of the mortality experience of workers exposed to vinyl chloride dating back to 1942.

Dr. Holder.

STATEMENT OF BEN HOLDER, M. D., OCCUPATIONAL PHYSICIAN, MEDICAL DIRECTOR, MIDLAND DIVISION, DOW CHEMICAL COMPANY

DR. HOLDER: Good morning. Judge Myatt, Mr. Klein, ladies and gentlemen:

My name is Dr. Ben Holder, and I am an occupational physician, presently as Medical Director of the Midland Division of the Dow Chemical USA.

I received a B.A. degree from Oberlin College in 1948, my M.D. degree from Wayne State University College of Medicine in 1952. I have been in the active practice of occupational medicine for twenty years.

Before I begin my formal presentation, I would like to thank Dr. Selikoff and his staff for the presentation of his clinical observations of some of our work population at the Midland location.

In previous discussions with the Mount Sinai group, we had hoped to combine our past medical records and industrial hygiene data with their recent test results prior to this hearing. Unfortunately, time simply would not allow.

I am primarily interested in their report because of my personal concern for the health of our individual employees. These have been my patients for twenty years.

I also feel that these clinical observations are of

the utmost importance to this hearing, and, because of this, I would hope that the record could be held open until we have an opportunity to combine our medical and industrial hygiene data with their data, to produce a meaningful environmental health report.

This combination of data will complement the Mount Sinai information so that a dose-response relationship may evolve. I believe this is the utmost importance and purpose of the hearing and I hereby request that we hold the record open until this information can be developed.

Today I would like to report on the long-term mortality experience of 594 chemical workers, exposed to vinyl chloride in a controlled industrial environment, between the years of 1942 and 1960.

No apologies, but in this report we recognize that our total population size is small and it does not readily lend itself to statistical analysis.

Our data on those workers exposed to vinyl chloride levels above 200 parts per million time weighted average suggests an apparent increase in the over-all malignancy rate. A decrease in malignancy was found where exposures were controlled below the levels of 200 parts per million time weighted average.

Again I think it is of particular note in our study, as we will refer later, that there were no angiosarcomas or other liver tumors found.

Now, the details of this work exposure were previously discussed by Mr. Daniel, and are in the record.

The population of interest was defined to be production employees at one manufacturing location -- Midlands, to be specific -- who worked in areas of potential vinyl chloride monomer exposure, between 1942 and 1960.

These employees were identified from annual departmental census lists. Through the annual census taken in January of each year, nearly all of the men who worked for at least one year, and about half of the men who worked for less than a year, would be identified.

The lists were reviewed over these specified years for five polymer production units. Exposure measurements, I believe as you've seen on the previous slides, were available for our two larger units, but not for three smaller units.

Determination of exposure categories were made prior and independent to the correlation of medical data.

To investigate dose-response relationship with respect to vinyl chloride, industrial hygiene data was reviewed for each job classification, and the job was assigned an exposure level rating of low, intermediate, or high.

The three categories were defined primarily based on estimated time weighted average concentrations for an eight-hour day TWA. The low level was defined as TWA concentrations below 25 parts per million vinyl chloride monomer; the

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intermediate was defined as 25 to 200 parts per million; and the high level was defined as 200 to 300-plus parts per million.

The high exposure level was also assigned to several jobs with time weighted average concentrations in the intermediate range, but where frequent unpredictable excursions above 1,000 parts per million were known to have occurred.

Changes in exposure level category for a given job, because of improved industrial hygiene practices, were properly recognized.

Since insufficient data was available to determine time weight average estimates for the three smaller units, a fourth category of indeterminate exposure was defined for individuals working in these areas.

943 An accurate and yet subjective evaluation of these three units by experienced industrial hygienists indicated that their exposures, for the most part, were in the low to intermediate ranges, with occasional excursion to high levels.

Because of job mobility, many employees experienced exposure at more than one concentration level. Individuals in the study group were assigned to exposure groupings based on the highest exposure experienced for one or more months.

This procedure insured that the lowest exposure group contained individuals experiencing only low exposure, with higher exposure groups, would have included individuals with mixed high and low exposures.

I believe you will see, through our entire methodology, that we are being extremely critical of our high exposure groups. I don't say this apologetically, but simply to define our procedures.

In the analysis, duration of exposure was separated into two categories: less than one year and one year or longer. This dichotomy was /because of the small number of individuals involved in the study.

For the intermediate and high groups, length of exposure at lower levels was not considered in assigning to individuals to less-than-one-year or one-plus-year category.

All right. Thus, an individual exposed at high levels for six months, and at low levels for ten years, would be classified in a high category with less than one year of exposure at that level. This category preserved the identity of the highest concentration level, rather than the cumulative dose.

Now, again, there's many ways of stacking the deck and cutting the cards; but this is the way that we felt that it was best descriptive.

Previous studies at this company location had indicated that individuals who worked in an arsenical production area prior to 1956 were liable to an excess cancer risk. A paper dealing with the mortality experience of the arsenical production employees has been submitted and is accepted for publication

and should be in the public press within -- professional press within a matter of months.

There were 72 individuals in the present study who were exposed to both arsenicals and vinyl chloride monomer. The mortality of the vinyl chloride cohort is summarized with the arsenical group included and excluded.

The arsenical employees have been excluded from tables that deal with dose-response relationships with respect to vinyl chloride.

A number of expected deaths were determined by summing the person-years lived by employees over the five calendar year period, ten-year age groups. The numbers obtained were then multiplied by the appropriate U. S. white male mortality rates and accumulated.

The U. S. data for the years 1942, 1947, 1952, 1957, 1962 and '67 were utilized along with projected rates for 1971.

Follow-up of employees who left the company was obtained through interviews, review of county and State records, and through the Social Security Administration information.

Copies of death certificates have not been obtained for two deaths among former employees. Each of these decedents had been exposed to vinyl chloride for less than one year. For this reason, the two deaths have been included in the all-causes category throughout the paper, but have not been apportioned to particular cause-of-death category.

Employment and vital status of the total cohort of 494 is presented in slide 4, by level of highest exposure. And I think it might be interesting just to run across this, and I will give you the feel here of the total population less arsenic. In the low area, 89 still working; intermediate, 42 still working; high, 100 still working; and intermediate, or undetermined, 38 still working.

In our retired population, 15 in the low, 12 in the intermediate, 16 in the high, 21 in the low. Deceased: 16 in the low, 8 in the intermediate, 20 in the high, and 13 in the intermediate. This is all in the record in much more detail for those interested.

As I said, 17 of 148 individuals who left the company were not successfully traced. 16 were not traced because, at the last minute, we expanded the original cohort population, and this was after we had our request in to the Social Security Administration. And this information will be forthcoming shortly, and I believe could be provided for the record at a later date.

One other individual was known to have left the country, and we believe is out of contact.

In other words, to date we have traced over 97 percent of our population.

Of 131 individuals successfully traced, 11 decedents and 59 people still alive were identified through interviews and

county death records. The remaining 61 employees were traced through the Social Security Administration. 11 of the 61 individuals were identified as deceased, and the remaining 50 were assumed to be living.

On Tables 5, 6, and 7 we summarize the mortality experience, by cause, of the total cohort population and of the population less those exposed to arsenic.

In our total population we had 88 observed deaths, with 96 expected. Of our total population 20 total malignancies, with an expected of 17.3. Less our arsenical population we had all-causes of 78, with an expected of 85.

Finally, with our total malignancies, which I think is the most important factor that we are presenting today, of our total malignancy experience, less arsenical exposure, we had an observed malignancy rate of 13 versus an expected of 15.4. I stress that point.

Now, let's break down our total malignancies, and what did we see in the profile? Again let's talk total population. Respiratory cancer: 7 observed, 5.6 expected. Abdominal -- in other words, digestive or peritoneal cancer -- 7 observed, 5.1 expected. All other sites, 6; 6.6 expected.

Now let's look at this without the arsenical exposure and we see under the respiratory, 4 observed malignancies with 5 expected; 5 under the gastro-intestinal, if you would use that broad term, 5 observed, 4.5 expected. 4, all other sites, with

5.9 expected, giving you a summary of the 13 observed and the 15.4 expected.

I believe it is also of some note to go on to other diseases, because these have been alleged to be associated with vinyl chloride exposure -- to some degree properly alleged.

Diseases of the cardiovascular system: observed 41, expected 47. And the other point I think of interest here is cirrhosis of the live; 3 cirrhosis of the liver in our total population, 2.9 for our expected. No difference there.

The total population less arsenic was essentially the same. For brevity, I'll omit this.

Seven of the ten deaths among the 72 individuals who worked with arsenicals were due to neoplasm. Only 1.9 deaths due to neoplasm were expected for this particular subgroup -- and I might give you a breakdown on the summaries of death of these seven individuals, who had both exposure to arsenic and vinyl chloride.

In the high exposure group we had two, one suffering from carcinoma of the lungs and the other of carcinoma of the colon.

In the low exposure group, we had two carcinoma of the lungs, one of the brain; and, in the indeterminate, one of the colon and one of the prostate.

As previously shown and discussed, three deaths due to cirrhosis of the liver occurred among individuals who left

the company prior to 1950. Again, the expected rate for our population was 2.9.

And these individuals were exposed to vinyl chloride for less than one year. One of these individuals, for whatever bearing it may have on his medical history, was discharged in 1948 for alcoholic intoxication. I really can draw no strong fact from that, but I think it should be entered in the record.

Again, no deaths due to angiosarcoma, hemangiosarcoma, or other liver malignancies were observed. Nor have their diagnosis appeared in the death certificates as secondary cause of death.

Again, as previously stated, our over-all total malignancies were less than expected, 13 versus 15.4 among employees exposed to vinyl chloride, but not arsenicals.

Now let's go on and review our data with reference to exposure levels and duration of exposure, which I think is of the utmost importance.

Clinical observations have their importance in, I believe, our hearing today, but without dose and without time they are somewhat lacking.

The mortality experience of the cohort, exclusive of the arsenical workers, was examined with respect to exposure groupings.

Table 9 shows the length of employment in areas involving vinyl chloride exposure in relation to levels of

exposure for each of the four exposure groups previously mentioned. A total length of exposure was less among the individuals in the low exposure group than among other exposure groups. 127 employees in the low exposure group worked for under one year in the production area of interest.

A probable explanation for this is that more entrance jobs were found in the low area.

Many employees, who remained with the units and established seniority, then worked into the higher exposure level.

Now, as far as duration of exposure, we have attempted to break this down in less-than-one-year, one-to-nine-years, 10-to-19 and 20-plus years.

Basically we have, I think, a quite representative spread in -- except in the 10-to-20-plus years of the low and intermediate grouping.

Here we have a relatively small population. However, we have, in the high exposure, a broad representation. I read this across: 33, 64, 39 and 27, from one-to-twenty years. In the intermediate-to-low group, 29, 38, but then at ten years we drop off to 6.

So our population is scant, of long duration on low exposure.

All right.

To allow for latent effects, latency or mortality

experience 15 years plus after initial exposure was examined in Table 12. Eight of the nine malignancies in the high exposure group occurred among individuals 15 years plus after their initial exposure. This factor and for a phenomenon has been previously discussed in the hearing.

On the other hand, only four malignancy -- or malignant deaths were observed among the remaining exposure group, with just one of these deaths occurring 15 years after the first exposure.

I might briefly summarize the table, and let's just talk about the malignant deaths, and not all-causes; all-causes are listed in the record.

Observed and expected death by exposure intensity, and duration of exposure -- excuse me. Observed and expected deaths by exposure and intensity of duration of exposure due to neoplasms, with the arsenic included and excluded.

I am going to go back here just a minute and come back to the latency, if you will excuse me.

951 A point that I wanted to make here in the duration of exposure, that I overlooked; observed and expected deaths by exposure intensity, and duration of exposure. Now, this is in the high exposure, and we're talking about malignancies.

Table 10. The observed was 9, and expected was 5. Now you see we have a higher incidence here than expected in the individuals who had a higher exposure. Higher duration of

exposure.

The same was observed in the arsenical group, where here we had 11 observed versus 6 in the high exposure. In our lower exposures, intermediate and unmeasured area, there was essentially the same as expected.

So, again, let me go back and point out: In the exposure of intensity and duration, we do see a significant increase -- excuse me. We see an increase of malignancy over that expected, both in the arsenical and non-arsenical group.

Now let's go on to the latency report, which we discussed here. Here again in the high exposure, with 15 years plus after their initial exposure, we saw an observed death from malignancy of 8, where it was 3.2 to be expected.

Case summaries of the 13 deaths due to malignant neoplasms are shown on Table 13. Seven of the 9 individuals in the high exposure group had worked for more than ten years in exposure areas; the remaining two worked for five to nine years. So these are not short-term employees in the high exposure group.

And I think it might be of interest -- again this is in detail in the record -- to give a breakdown of the cause of death and some information regarding the cause of death of our population. By the way, this was substantiated approximately by -- approximately 40 to 50 percent autopsy information; the rest from death certificates.

In the high exposure: cancer of the stomach, cancer of the lung, cancer of the lung, cancer of the rectum, cancer of squamous cell [site undetermined], leukemia, cancer of the lung, cancer of the lung, and cancer of the colon.

In our intermediate group we had two: cancer of the brain and the pancreas. The low group: one cancer of the lung; and in the indeterminate, one cancer of the lung.

Their ages of death in the years following initial exposure -- I'll just run down through the highs to give you a flavor of this: 14, 17, 17, 26, 28, 21, 27, 22, and 25 years after their initial exposure.

Full details will be in the record.

Two deaths from neoplasms were recorded on death certificates as a secondary cause of death. Each death was coded in the category of diseases in the cardiovascular system. However, I think it is appropriate to cite these two deaths.

One death, the immediate cause of death was an acute myocardial infarction; however, a secondary disease of bronchiogenic carcinoma existed. He was in a low exposure group for three months' duration.

The other one was again a myocardial infarction, with a cancer of the sigmoid, or the colon, and he also was of a low exposure group.

Now let me go on and make a few, I guess I will say my opinions: One must, I think, truly consider vinyl chloride to

be a carcinogen.

However, I do feel it's appropriate to mention several other observations that we have made that would give support to the possibility of this material being an immunio-suppressant or a co-carcinogen.

Again, I fully recognize that our data is limited, and I present this posture only to stimulate further thought and possible research among the scientific arena. And this data refers back to our 13 deaths on Table 13.

One, an interesting case of acute granulocytic leukemia. During the last ten years of his employment he was not exposed to vinyl chloride, but worked in an area of benzene exposure -- controlled benzene exposure. And I think one work area, the highest excursion, only infrequently, was 50, the rest is well below the TLB.

The case of adenocarcinoma of the rectum, severe familial history: mother, two brothers and one sister died of this malignancy.

Three, of the total four lung malignancies in the high exposure group, three and probably the fourth had a history of significant cigarette smoking.

Again this raises the question as to the advisability of smoking, particularly when working with environmental carcinogens, be they vinyl chloride, asbestos, or what-have-you.

Lastly, in support of this postulate, additional

support could be gained in recognition -- again in recognition of the small population. But there were seven malignancies in the group exposed to arsenic and vinyl chloride.

Again, as I mentioned before, an expected of 1.9.

Now, the SMR, or Standard Mortality Ratio, for malignancies of our total vinyl chloride population, excluding arsenic, would be 0.8. However, the SMR with a population of vinyl chloride plus arsenic was found to be 3.6. I think a factor that we can't completely ignore.

All right. In conclusion, our over-all mortality of our experience of our population was better than the expected for the U. S. white male population. Again, 13 to 15.4. No angiosarcomas, hemangiomas, or liver tumors were found. No adverse effect from malignancy was demonstrated in the population where exposures to vinyl chloride were controlled below 200 parts per million time weighted average.

In workers exposed above 200 parts per million, time weighted average, an increase in over-all malignancy experience was noted.

Thank you for your patience.

MR. ROBB: Thank you, Dr. Holder.

Now I would like to ask Dr. Perry Gehring to come to the table.

Dr. Gehring is Director of the Toxicology Research Laboratory of Health and Environmental Research for Dow Chemical

USA, and he will present and discuss data we have so far obtained relative to the metabolic pathways by which rats deal with vinyl chloride monomer.

Perry.

STATEMENT OF DR. PERRY GEHRING, DIRECTOR, TOXICOLOGY RESEARCH LABORATORY OF HEALTH AND ENVIRONMENTAL RESEARCH, DOW CHEMICAL USA

DR. GEHRING: Judge Myatt, gentlemen:

I am Perry Gehring, Director of the Toxicology Research Laboratory for the Dow Chemical Company USA.

I graduated in 1960 from the University of Minnesota with a Doctor of Veterinary Medicine degree. Subsequently I entered graduate school and received my Ph.D. in 1965, with a major in pharmacology and a minor in physical chemistry.

Immediately I took a job with the Dow Chemical Company as a toxicologist. In 1968 I left Dow and took the position as associate professor of pharmacology at Michigan State University. In 1970 I returned to Dow as Assistant Director of Toxicology Research. I still retain a position as visiting professor in the Department of Pharmacology at Mighican State University.

I have authored or co-authored over 40 publications in the field of toxicology, and have presented in excess of 20 papers at scientific meetings.

I am a member of the Society of Toxicology, the

American Society of Pharmacology and Experimental Therapeutics, and the New York Academy of Sciences.

Currently I am serving on the editorial board of the official journal of the Society of Toxicology: Toxicology and Applied Pharmacology.

The basis for my testimony is the results of preliminary studies conducted in the Toxicology Research Laboratory at the Dow Chemical Company by Mr. Robert Hefner, Dr. Philip Watanabe and myself.

These studies were initially supported solely by the Dow Chemical Company. Recently, support has been by our contract with the Manufacturing Chemists Association.

The results of the studies were reported at the Vinyl Chloride Workshop sponsored by the New York Academy of Science, and the manuscript has been submitted to the Academy for publication in the Annals of the New York Academy of Science.

Copies of the manuscript, which has been submitted for publication, will be conveyed to you -- and, indeed, you already have it.

With exception of my attempts to elucidate the potential significance of what appears in that manuscript to the promulgation of work standards, the bulk of my testimony is contained in the manuscript, together with the experimental details.

I want to re-emphasize that these studies are prelimin-

ary, although conceptually important. Many of the boundaries for the ultimate interpretation of our results remain to be resolved by future studies, some of which are now underway.

Nonetheless, what we have discovered today must be considered in using a rule-of-reason approach to setting standards for vinyl chloride.

The primary objective of our studies is to elucidate the fate of vinyl chloride monomer in the body, first in rats, then in other species, and ultimately in man.

Upon learning of the carcinogenic effect of vinyl chloride, we considered the possibility that this action may occur by a direct reaction of vinyl chloride with the nucleophelet groups of protein, DNA, RNA.

Initial attempts to react vinyl chloride with the nucleophelet sulfhydryl groups of cystine and glutathione in vitriol revealed a slight reactivity, but only under conditions considered too rigorous to be of consequence in the body.

This was consistent with our expectations, though, therefore we hypothesized that vinyl chloride may not be the ultimate or even the proximate carcinogen, and that the ultimate carcinogen is very likely produced by the degradation or metabolism of vinyl chloride in the body. This concept places a high priority on elucidation of the metabolism of vinyl chloride.

As a possible pathway for the degradation of metabolism

we hypothesized that the same pathway utilized for the metabolism of ethanol may be utilized -- that is, alcohol dehydrogenase.

If this is the case, it may be expected that the metabolites would react readily with the sulfhydryl containing amino acids, and, most importantly, that upon exposure to large amounts, the metabolism of vinyl chloride, like ethanol, by the alcohol dehydrogenase pathway, may be saturated, swamped, or overwhelmed.

If this occurred, the metabolism of vinyl chloride may be shifted to another pathway.

These thresholds for metabolic degradation of the compound must be known and considered before intelligently utilizing available toxicological and epidemiological data to establish standards for vinyl chloride, which optimize the benefit/risk relationship, however with reason.

Before I proceed with the results of our study, allow me a few more minutes to illustrate why thresholds for degradation are critical to assessing hazards.

This slide -- you cannot read the caption. Essentially what I have done here is to represent the body by a barrel, the exposure by an input source -- this being a faucet -- and the output source either by a metabolism or excretion being represented by slits, triangular, in the barrel.

If the rate of inflow is slow, as seen in the upper left, then essentially all of the material can exit from this

barrel by the slit in the lower right. As the input becomes larger, then we eventually swamp, overwhelm the first outlet means, and it begins to flow through another. And of course this can go on until we have actually swamped both outlet means.

Now, these are two and in the body there can actually be many of these.

Many substances have been shown to exhibit this type of phenomena, including aspirin, ethyleneglycol. In fact, ethyleneglycol, for example, in very low doses is metabolized completely, carbon dioxide. If you give larger doses, it is metabolized in a fashion that leads to the excretion of oxylate in the urine and these nitoses of material eventually lead to the production of bladder cancer in animals.

Thank you for your indulgence, and now let's proceed with the results of our preliminary studies.

The first thing we did was to determine -- I guess, first, let me show you just a brief bit about the methodology.

In this study our objective was to measure the rate at which rats metabolize vinyl chloride. This slide shows a system with which we made these measurements. You can see some rat bodies in tubes, and their heads protrude through a diaphragm into the chamber.

This is a closed system and the only exit of the vinyl chloride is due to the slow background leak, plus what the rat metabolizes. And both of those occur by first order

rates, and so you can determine the rate at which it metabolizes if you know the rate of loss from the chamber.

As the rat expired CO-2, it was picked up in an ascarite column and then makeup oxygen was injected automatically.

We monitored continuously the rate at which the vinyl chloride was removed from the chamber via a Myron-1 infra-red analyzer.

Now let's go to an experiment, and here we have an experiment in which rats were exposed to between -- somewhere between 70 and 80 parts per million, as indicated by the ordinant here.

And then the disappearance, the rate of disappearance is indicated by the steepness of the slope. The upper curve or the upper line shows the rate at which it was cleared from the unoccupied chamber; and the lower, the rate at which the rats, with the rats in there, in other words, the rate at which they metabolized it.

In 7 separate experiments, at concentrations ranging from 50 to 105 parts per million, the rate constant for removal was 3 plus or minus 3 times 10 to the minus 3 minutes to the minus 1. This corresponds to a T-1 half-life of 86 minutes.

Now, when we went to the higher concentration, we found something quite different. Here the rats were exposed to near 1,000 parts per million. Again we have the rate at which the material was removed from the unoccupied chamber, and then

the rate at which it was removed from the chamber with the rats in it.

In five experiments, at initial concentrations of 220 to 1167 parts per million, the rate constant for disappearance was 2.6 plus or minus 1.3 times 10 to the minus 3. This corresponded to a T-1 half-life of 261 minutes; considerably longer.

So we do see, then, that -- I should also say at this higher concentration of 220 to 1,000 there was no consistent increase in this rate. Once you got above that level, it was the same rate constant, which indicates that above this level whatever mechanism is the secondary one is essentially the same, between these particular exposure concentrations.

So what we have demonstrated by this initial two studies, rather definitely is the fact that vinyl chloride is metalized by rats rather rapidly when exposed to low concentrations. However, when you exceed 220 parts per million in this case, the rate of metabolism is much slower but still first order.

Now, we had hypothesized, as I indicated, that it couldn't possibly go through the alcohol dehydrogenase pathway. And a known inhibitor of alcohol dehydrogenase is pyrazole, and so we gave this material to rats. And here we have the unoccupied chamber again, rats that were pretreated with pyrazole, and the untreated rats in the line with the steeper

slope. As you can see, pyrazole caused a rather marked inhibition at the rate at which rats metabolize this compound.

In fact, using the rate constants again, the inhibition was 71 percent, when the initial concentration was 65 parts per million. We also did this same type of experiment using the higher concentration of 1,000 parts per million, and again the pryazole caused an inhibition, which you would expect, because some would still be going through the alcohol dehydrogenase pathway; and, in addition, pyrazole does inhibit more than the alcohol dehydrogenase pathway; zambiene oxydase is another example.

To determine whether or not this was metabolism by the alcohol dehydrogenase pathway more specifically, we administered alcohol. And here are shown results of that.

The untreated rats again removed the material from the chamber very rapidly, whereas ethanol almost inhibited this. 56 parts per million in initial concentration, there was 96 percent inhibition; another experiment had 97 parts per million, there was 33 percent inhibition.

Going to the higher concentrations, the inhibition by alcohol was much less profound. At initial concentration of 1,025 parts per million and one experiment, the inhibition was 46 percent. In another experiment, at 1,034 parts per million, the inhibition was 36 percent.

So we have, upon these experiments, that we can con-

clude that vinyl chloride is metabolized by alcohol dehydrogenase, and its metabolisms at low concentrations may be profoundly black, wherein it is not black, so that profoundly higher concentrations, which again indicates that there is a second pathway involved.

We did feel the possibility that the second pathway may be due to the microsomal oxydation, by the mixed function oxydases. There is an inhibitor of this pathway, and we gave SKF-525-A to inhibit, if possible, at least one aspect of this pathway.

Here you see exposure to concentrations between 60 and 70, again where the alcohol dehydrogenase predominates, and SKF-525-A did not produce any black.

However, it's hard to see here, but this has been duplicated in two experiments. When you give it to animals exposed to the high concentration around 1,000 parts per million SKF-525-A does cause a black.

Another experiment which we conducted, and I'm just going to spend a very brief time on here, is we have exposed rats for varying periods of time, seven hours per day for periods of one week, one, three, and seven weeks, to 500 parts per million; so we've varied both the exposure duration and exposure time. And then measured, subsequent to the last exposure, the sulfhydryl groups in the liver, both the protein and non-protein pre-sulfhydryl; namely glutathione and cystine.

We did this because we felt that one of the mechanisms of vinyl chloride may -- well, the metabolism of vinyl chloride by alcohol dehydrogenase produces compounds which react with these non-protein pre-sulfhydryls. And, as you can see here, exposure did cause an inhibition, or a lowering of these non-protein pre-sulfhydryl groups in the liver.

An important thing to recognize, however, is that with exposure, with the exposure duration extended, there seems to be an adaptation. This is not a dose-related response, obviously. 500, 5,000 and 15,000 do not really cause perceptible differences, and there did seem to be an adaptation.

I think this is important, because it has been said previously that vinyl chloride may be the ultimate carcinogen. And if vinyl chloride was the ultimate carcinogen, as Miller, at the University of Wisconsin, has stated, and many other people now, is that it is the electrophylic capacity. If the vinyl chloride was truly that electrophylic and that activated in the body, you would expect a very profound dose-response relationship here. In other words, that the inhibition would definitely be related to the dose, rather than as it is.

We also examined -- excuse me. Let me tell you about initial attempts to identify metabolites before getting into this.

We did examine the urine for metabolites. We have identified S-2 hydroxyethylcysteine in the rats from the previous

experiment. We also, after exposing them to 5,000 parts per million for nine weeks, we did find monochloracetic acid. We have not found it in some other subsequent experiments.

These were by -- I caution you, these were by cold methods, and so we were using thin layer chromatography, and we really have to define the boundaries of our preconceptions before we can definitely state that those are two metabolites.

We have conducted initial study using C14 vinyl chloride. Unfortunately, we don't have more results, but we found that C14 vinyl chloride polymerized very readily.

We did expose rate to 49 parts per million vinyl chloride for 65 minutes, and then, during which time they received about 5/10th of a milligram per kilogram dose, and then subsequently we removed these animals immediately from the chamber and put them into a Roth metabolism cage, which allowed the separate collection of urine, feces and expired air.

Within 15 hours, 58 percent of the C14 activity had been excreted in the urine, 3 percent in feces, 10 percent as expired carbon dioxide.

By 75 hours, the respective amounts excreted by these routes was 67, 4, and 14 percent.

Rats were killed at the end of those 75 hours, and we found 1.6 percent of the dose of C14 radioactivity given as vinyl chloride remained in the liver, 3.6 in the skin, which

was probably due to contamination and with the urine and so on, 2/10ths of a percent in kidney, and 7.6 percent in the entire remaining carcass.

I emphasize that this residual was C14 activity, not vinyl chloride. Since vinyl chloride was metabolized totally to carbon dioxide, obviously the carbons from the vinyl chloride do enter the general carbon pool, and these could be part of protein -- in other words, they are all over, and could be in many, many different types of substances in the body.

With regard to metabolites in this experiment, again we have essentially, initially identified two hydroxyethylcystine, two carboxyethylcystine, and the NS steel derivative of these; however, we do have to verify these by gaschromatographic aspect analysis.

We did not see monochloracetic acid. And again, this is important, because monochloracetic acid was not seen at the low dose, but was seen at the high, which indicates that there is alternate pathways possibly occurring.

If you would turn that on again, Ted, I would like to run through the conclusion. In rats exposed to 100 parts per million or less, of vinyl chloride, the compound is metabolized readily by the alcohol dehydrogenase pathway.

Vinyl chloride metabolism by this pathway is satiable and inhibited by ethanol and pyrazole, but not by SKF-525-A.

In rats exposed to 500 parts per million or greater

of vinyl chloride, the compound is metabolized at a slower over-all rate than in rats exposed to 100 parts per million vinyl chloride or less.

However, metabolism at the higher level still follows apparent first-order rate kinetics and is partially inhibited by SKF-525-A, in addition to pyrazole and ethanol. Therefore, metabolism by the secondary pathway may be via the mixed function oxydase system of the microsome.

Exposure of rats to 50 to 1500 parts per million causes significant reduction of the non-protein pre-sulfhydryl content of the liver. The reduction is not related to the magnitude of exposure and becomes less pronounced, indeed insignificant, when continued -- with continued repeated daily exposure.

This is the biggest one. If you will bear with me. Preliminary attempts to identify metabolites have revealed carbon dioxide, S-2 hydroxyethylcystine, S-2 carboxymethyl-cystine, as well as NS steel derivatives.

Monochloracetic acid was found in the urine of rats exposed repeatedly to 5,000 parts per million, but not in rats exposed once to 50 parts per million.

Carbon dioxide derived by vinyl chloride is excreted in expired air. The other degradation products are excreted in the urine.

Following exposure to 50 parts per million vinyl

chloride, most degradation products were excreted within 15 hours. After 75 hours, about 11 percent of the total dose remained in the body, probably as metabolites. The liver had a somewhat higher level than other tissues.

As a guide to future studies we have hypothesized these pathways shown in this slide -- I'm not going to dwell much on this. The top pathway is alcohol dehydrogenase, and unfortunately the artist left out a couple of arrows.

The intermediate one is a catalase system, which has been reported in the literature and does produce peroxides, which again could produce the ultimate carcinogen.

The one that is somewhat appealing to me is the lower pathway. This is pretty far-out speculation, I suppose, but I think it is important that inorganic arsenic and thorotrast are two materials known to cause angiosarcoma.

Arsenic also causes other lesions like that of vinyl chloride. Some of the skin effects, the peripheral nervous disorders, and so on.

In 1956, Gonzalez demonstrated that the biochemical lesions associated with arsenic poisoning was a reaction with 6 8-dythiooxinoid gas or alfalapoic acid.

If the epoxydase, this compound that the ethylene, chloroethylene oxide is formed, this would be a natural product that could be formed through the epoxydase pathway. It, too, would react with alfalapoic acid or arsenic, bridging the two

sulfhydryl groups and forming quite a stable compound.

And this compound, incidentally, has been reported in literature, so it is stable enough not to be too transient to invoke such possibilities.

Although much of what I have presented is preliminary and speculative, I do feel our results have demonstra-ed a few points which should be considered in setting standards for vinyl chloride.

To emphasize these, let's return to the concept of metabolic degradation and elimination, as represented by the barrel, Slide 17.

Our preliminary data support the presence of at least two slits in this barrel, one of which may be saturated as the barrel fills. As this barrel -- that is, the body -- fills or the rate of input becomes larger, more of the compound is degraded by the second slit.

If the concentration is less than 100 parts per million, the bulk of the vinyl chloride appears to degrade by the lower slit. Concentrations greater than 200 parts per million, degradation by the upper pathway becomes prominent.

Although I feel degradation of vinyl chloride by the upper pathway may lead to the production of the carcinogen, it is only speculative at this time, since degradation by the lower pathway may also produce the culprit. However, this speculation is consistent with both the available toxicological

and the available epidemiological data.

Indeed, using classical statistical approaches, it is not scientifically sound to use toxicological or epidemiological data obtained by the administration of amounts or exposures exceeding thresholds to predict what will occur at lower concentrations or lower exposures.

In other words, Dr. Schneiderman pointed out the other day that things don't drop off the edge of the table. I talked to Dr. Schneiderman following that discussion, and what this data shows, or show -- what these data show is that things do indeed drop off the end of the table.

You cannot compare the two situations when you have, when you are below a threshold versus when you are above it. Here we have definite evidence for a metabolic threshold.

Such attempts to make these statistical projections, then, not only violate, I feel -- not only violate the basic a priori assumption for statistical analysis of data, but common sense as well.

Therefore, these preliminary results should be given serious consideration, and using rule-of-reason, to optimize the benefit-risk relationship in developing the standards.

Thank you.

MR. ROWE: Judge Myatt, in summary, I would first like to redirect your attention to that portion of Dr. Gehring's presentation wherein he referred to studies which

have been undertaken to provide a basis for a better understanding -- for better understanding the mechanisms of action of vinyl chloride monomer.

Preliminary data suggests that the material may be metabolized via different routes, depending upon the magnitude of exposure. The possibility that the ultimate carcinogen may be a metabolite formed by a second or even a tertiary pathway when the primary pathway is swamped, is speculative but should not be disregarded without testing.

Similarly, the possibility that the material, per se, or a primary metabolite is directly responsible for the carcinogenic action also needs to be determined.

It also seems absolutely necessary to us to determine which animal species is most like man, in its metabolism of vinyl chloride monomer; so that that animal species can be used in future toxicological work with vinyl chloride monomer.

At present we do not know how much significance to attach to the dose-response data being derived from the various species being studied.

Answers to these questions are urgently needed. And we urge that others also put their shoulder to this wheel as rapidly as possible.

Next I would like to re-emphasize the following points made by previous speakers, which we feel are supported by the long and favorable experience of the Dow Chemical

Company in the manufacture and use of vinyl chloride.

In keeping with our practice to keep concentrations as far below any OSHA standards or self-imposed guidelines, as is reasonably feasible, the Dow Chemical USA is generally operating within an eight-hour time weighted average concentration of 10 parts per million.

However, brief malfunctions and other temporary situations occasionally result in short-term concentrations in excess of ten parts per million.

Based on the data we have, we believe our plants are being operated in an appropriate manner.

Specific situations should dictate the selection of respiratory and protective equipment. Effective cartridge and canister masks are available and should be permitted in situations where rapid egress may be necessary and/or where the air concentration is continuously monitored and shown to be below 50 parts per million.

Excessive requirements for the use of respirators and protective clothing may well result in increased risk and injury to workers due to stress and impairment of vision, hearing, mobility, dexterity and agility.

Provisions should be made for continuous area monitoring, in addition to personnel monitoring. Continuous area monitoring provides the early detection of equipment failure, and, when equipped with an alarm system, alerts the

employee so that appropriate protective equipment can be used to prevent exposure.

The monitor also provides data which is useful in calculating employees' exposure on a time weighted average basis. The analytical method selected for monitoring will depend upon each plant situation. Only someone familiar with the plant situation can design an appropriate monitoring system.

Periodic medical examinations and clinical studies indicate no evidence of any adverse effect on any organ system attributed to vinyl chloride in a population with random plant exposures up to 200 parts per million.

We have had no cases of acroosteolysis in our work force; nor in exposures up to 200 parts per million have we seen any medical abnormalities attributable to vinyl chloride.

When data from workers who were in Dow's high exposure category are separated from the rest, there was a suggestion of an increase in deaths due to malignancy: 9 versus 5.1. However, when the whole population exposed to vinyl chloride was considered, there was no difference.

We have found no evidence of any deaths due to angiosarcoma or liver malignancy of any kind in our workers exposed to vinyl chloride.

We can only conclude that the absence of the signs and symptoms noted must be associated with the over-all low exposure levels our employees have experienced.

AFTERNOON SESSION

(1:50 p.m.)

JUDGE MYATT: All right, ladies and gentlemen, the hearing is resumed.

MR. KLINE: I have a few questions for Dr. Holder and Dr. Cooke.

Dr. Cooke, could you indicate to us the basis upon which you selected this one plant as your study group?

DR. COOKE: This was an interim, midland location. It was a matter of convenience because we had access to both medical and industrial information.

MR. KLINE: Do you consider the numbers of employees examined to be statistically significant, in terms of the overall total exposure, employee exposure?

DR. COOKE: I am not a statistician.

MR. KLINE: Do you have a view on it?

DR. COOKE: No, I would leave that to Mr. Edelson.

MR. KLINE: Now, in your testimony, you indicate that there was an analysis of the selected health surveillance data.

Could you tell us what you mean by the term "selected"?

DR. COOKE: Well, as I mentioned, we measure more than 40 or 50 variables and we chose to select variables out of that.

We chose to select particular enzymes studies and

the questions we felt pertinent to this particular problem.

Mr. KLINE: But the selected aspect was not as to the employees, that was all of the employees.

DR. COOKE: The selected aspect for this study was for the exposure groups and an air control -- and I have already defined why we determined the matched air control.

MR. KLINE: I was a little confused. Why did you use air control?

DR. COOKE: What we did was use individuals who had also gone through the health surveillance study at the same time. We matched them with an age. In other words, if we had a man who was 45 years of age in one of the exposure groups, we matched him to another individual who also was 45, or roughly that age, who also had a similar smoking history, who also, you know, etcetera, etcetera.

MR. KLINE: And, from -- did the control come?

DR. COOKE: From our industrial population.

MR. KLINE: These people work with various chemicals over the years?

DR. COOKE: The tracking of their chemical exposure was not determined.

I would anticipate that they probably had some chemical exposure somewhere, probably with the exception of office workers. So this was not considered in the protocol, per se.

So, this was not considered in the protocol, per se.

Mr. KLINE: How old is the midland plant?

DR. COOKE: I have been there two years and it was there before me. Somebody else would have to answer that.

(laughter)

MR. KLINE: Mr.Rowe, can you give us an idea?

MR. ROWE: If you mean the midland plant, per se, over all --

MR. KLINE: With respect to VC.

MR. ROWE: Well, with respect to VC, I think these first activities were in about roughly 1940. I don't know just where the transition came about, from the standpoint of research in the laboratory to production.

I think research actually began in the late '30's, perhaps 1939, but since then it has been in one stage of development or the other.

MR. KLINE: Thank you.

Doctor, do you know what percentage of employees have exposure of over 15 years? Was that taken into account in your study?

DR. COOKE: No, I didn't take that into account in my particular study.

I think Dr. Holder addressed himself more to duration of exposure than I did.

The only duration of exposure we did, we refined

these as individuals who had more than one year of exposure so they were not transients.

MR. KLINE: In light of latency period, do you see any problems with your failure to take into account all exposure periods?

DR. COOKE: Well, it depends on what effects we are looking for.

Essentially, we were looking for the acute effects of exposure and also we were picking up the possibility of screening for malignancy.

MR. KLINE: On page 3 of your testimony, you have indicated that you took the employees who were there since February of 1967 to March 6, 1974.

Was that based exclusively on the medical data available?

DR. COOKE: February of 1967 is when we started the medical health inventory. March of 1974 is when we (inaudible)

MR. KLINE: So, I take it, it is just a matter of availability of information that you took that time.

DR. COOKE: Yes, we defined this as production employees. This is when the data on production employees was available.

MR. KLINE: Dr. Holder, in judging your results of the mortality tables, what do you infer that the mortality rate, of the lower mortality rate and the lower malignancy

experience?

DR. HOLDER: I have no inference, just the observation that the lower exposure group fell below the expected level of mortality experience. In facts, the facts stand for themselves.

MR. KLINE: Do you attach any significance to your study?

DR. HOLDER: That in lower exposure of vinyl chloride we did not see any indication of malignancy, in fact decreased rate of malignancy.

MR. KLINE: Do you think that should be used as a basis for inferring in the future there should also be lower rate of malignancy, or do you feel the statistical population is not that large enough to make that inferance?

DR. HOLDER: I believe I qualified my report several times. We are working with 594, which is not a large group of people.

However, I think it is a significant study, and one of the few studies in which a close relationship is associated with experience.

It is a value judgment, Mr. Kline.

MR. KLINE: Yes, I understand.

DR. HOLDER: I mean, 10 is fine, 100 is better, and 1,000 would be wonderful.

MR. KLINE: Now, you have indicated that you think

five polymer production units -- is there any particular reason why you picked those 5 units?

DR. HOLDER: They were all units in our location.

MR. KLINE: Do you believe there is a safe level with respect to vinyl chloride, based on your studies?

DR. HOLDER: Our data would indicate that below 200 ppm there is no adverse effect; that we happen to find you can't define safe period.

MR. KLINE: Could you define it for us?

DR. HOLDER: I am afraid I am not in that position today.

MR. KLINE: I believe Dr. Lassiter has a few questions.

DR. LASSITER: First, Dr. Cooke, in part of your testimony here, you reference the (inaudible) study.

In your testimony, you put their findings or their conclusions of the study. This was a study, I believe, of fairly short-term duration, was it not?

DR. COOKE: What do you mean?

DR. LASSITER: About six months exposure, or something like this, or could you give me the exposure that they used to draw their conclusions?

DR. COOKE: It is my understanding that they were drawing from a population from 1942 to 1972 and 1962 or, well, when the examinations were done, so it was pre-1967, but

started -- an exposure period of about 1952.

DR. LASSITER: Okay, on page 3 of your testimony, does this represent two separate groups we are talking about here, or one group?

DR. COOKE: A population of interest?

DR. LASSITER: Yes.

DR. COOKE: It is one group.

DR. LASSITER: At midland?

DR. COOKE: Yes.

DR. LASSITER: Okay, well, the total study, then, involved individuals who were exposed, as I see it, between 1967 and 1974, is this correct?

DR. COOKE: No, the health inventories were done between 1967 and 1974, is this correct?

DR. LASSITER: No, the health inventories were done between 1967 and 1974. That is the inclusive period of multiple health screening.

DR. LASSITER: Okay, so only individuals that were part of that health inventory were included in that study?

DR. COOKE: All we looked at was the health data out of a population we defined from 1942 on.

DR. LASSITER: Could you give me some type of a breakdown as to how many other people in the study were exposed, say,as to 10 years or 20 years?

DR. COOKE: I do not have the data with me. That was

that was not part of our initial protocol.

DR. LASSITER: Just, in general.

DR. COOKE: I have no idea. I can try to analyze that and give you some information later.

We defined it as individuals who had more than one year but, beyond that, I don't have a definition.

DR. LASSITER: Is it possible that you could make this available to us so that we could see at least in five years increment what percentage of the population?

DR. COOKE: I will attempt to get that to you.

DR. LASSITER: I think we agree this should be an important statistic in your findings.

DR. COOKE: It would be an interesting statistic.

DR. HOLDER: That information is available and will be made available for the record.

DR. LASSITER: Thank you.

Dr. Holder, I believe you said, in your testimony, you made the statement you felt vinyl chloride was a carcinogen.

DR. HOLDER: Yes.

DR. LASSITER: I think you are talking about an even percentage, now.

DR. HOLDER: Yes.

DR. LASSITER: Now, on the basis of your studies and on the basis of your study extending the question that

was asked by counsel here, do you feel that your study would prescribe a safe level of exposure, or it fails to prescribe a safe level of exposure, or is there some doubt as to what the study would do in this area?

DR. HOLDER: No, I think a safe level of exposure or when you are establishing an exposure level, say, definition requiring mulitple disciplines, and I don't think my singular document here should be used to establish a level.

This is simply a segment of information to be presented to this hearing, Department of Labor, to come up with "safe level."

Health is a multi-discipline factor, and this is simply of medical epidemiological importance.

DR. LASSITER: Do you believe arsenic causes cancer in humans?

DR. HOLDER: Yes, without consulting the literature and our forthcoming article.

DR. LASSITER: We had an epidemiological study report to us by Dr. Peters.

Was this the Midland Report?

DR. HOLDER: No. I talked to Dr. Peters afterwards. This was not the midland plant.

I believe, to the best of my understanding, and this is a very cursory understanding, that this was the Goodrich, in Kentucky.

DR. LASSITER: I am sorry?

DR. HOLDER: Goodrich, Kentucky. That is what we are referring to.

I might help you out here a little bit in your question.

To the best of my knowledge, we have contributed our data to the Cooper data.

To the best of my knowledge, that is the only other area in which data has been used other than our own internal publication, which I just presented today.

DR. LASSITER: Thank you.

I have several questions I would like to ask Dr. Gehring, if I might.

First of all, I compliment you on a very in-depth study. I wish this was true of the industry, as a whole, but I think they ought to be commended for going in this area, and what I have to ask is for information so we can better understand it.

First, I realize your results are of a preliminary nature and when I get a chance, later on, when I have a chance to digest it, I might have some other questions, but I mainly have some questions about your protocol, and some of your conclusions that you have.

In general, you have suggested methods for vinyl chloride, one which would operate under circumstances of low

concentrations, and the other one when this overwhelmed, so to speak. It would be shifted to the methocthelyn pathway.

Do you consider your study considering this pathway methocthelism with vinyl chloride is statistically significant in your studies?

DR. GEHRING: The second pathway?

DR. LASSITER: Yes.

DR. GEHRING: I think the answer to that question is yes, if you look at the data in toto.

For example, like I said, we ran seven experiments, each consisting of four mice and 100 parts per million, or less, and five experiments consisting of four rats apiece at 220 ppm greater and the rate consequence within, when you compare those two ranges, is quite different.

Also, we blocked the one with alcohol, whereas, we couldn't block the other, so that is an additional level.

The 2F25-A is certainly not statistically significant at this time, and it would have to be considered as an indicator, but to repeat, the existence of two pathways, I think, is very definite.

DR. LASSITER: Okay, thank you.

Looking at your animal studies, did you have controls only? I see several unexposed groups. For example, I was a bit concerned, in looking at the setup in the metabolic cages, that there would be a stress effect, definitely, with rodents.

Do you have some untreated, unexposed, animals that you also subject to this? In other words, unexposed controls?

DR. GEHRING: Do you mean put the rodents in a cage?

DR. LASSITER: Right.

DR. GEHRING: Without any --

DR. LASSITER: I am worried about a stress effect per se in confining these animals to a small space. It is pretty well known.

DR. GEHRING: Well, that is true. These were short. I guess the best answer to that is the fact that we exposed animals all the way from, I believe, somewhat less than 40 minutes up to eight hours, and followed the rats over this entire period of time in some of the initial experimentation, and it didn't change.

It is true when you get to the end of that, you are going to be getting a few steroids, and so on, which we did ultimately.

DR. LASSITER: Did you use unexposed controls, as it were, to obtain base line data?

Base lines, for what?

DR. LASSITER: Well, for any of your conclusions here. In other words, I see you have untreated controls, and these would be your baseline measurements.

DR. GEHRING: That is right.

DR. LASSITER: You mentioned here that some kind of

compensatory mechanism that might account, I suppose, for the return to lower values at your normal exposure levels.

Could you give any idea what you think this might entail?

DR. GEHRING: No, I really can't. I thought about it considerably and we intend to pursue that.

It is a very interesting phenomenon, which we have looked for in the literature. There is absolutely no reference to such thing as that.

Those studies were among the first studies one conducted and we definitely are very interested in that from the basic science aspect, not just vinyl chloride.

DR. LASSITER: You indicated in your studies that although there is -- most of the vinyl chloride is metabolized and eventually comes off as carbon dioxide, but that a small amount is retained in the organ.

Although it is a small amount, what form do you think this appeared in the organ? And, perhaps, does it appear in some of the metatabolites you have isolated with DLC?

DR. GEHRING: Yes, it could be metatabolites that we have already found some evidence for.

What remains to be done, of course, is to continue this work and determine their extractability and what exactly they are.

I would point out that we conduct a large number of

C-14 metabolism label experience, drugs or potential drugs and other materials in our laboratory, and you know, that is one of the hazards of the trade, that when you get something that enters the carbon pool, when you get down to that last bit, it is incorporated in protein and other factors that sometimes it is impossible to isolate these things.

DR. LASSITER: Would you consider that the retaining forms to deliver would be -- you characterized these as intercellular compounds.

DR. GEHRING: We have to determine that. I assume that would be both.

DR. LASSITER: Would it be possible that these compounds could be, in some way, attached to either PRN or DNR of the molecular structure?

DR. GEHRING: Yes, of course.

DR. LASSITER: You mention, on page 15, for a point of information, in a discussion that the impact of some recently revealed toxicological effects of VC. Are these the carcinogenic effects that we have been talking about today?

DR.GEHRING: Yes.

DR. LASSITER: You mentioned particularly a couple of non-protein self-hydro compounds in connection with your study.

Have you observed any other such compounds besides the small sistine molasic type of compounds, such as the

points I made?

DR. GEHRING: No, we have not.

DR. LASSITER: Is it possible that finding could also take place via other such compounds?

DR. GEHRING: Yes, it would be phosboric acid as a possibility.

DR. LASSITER: Have you looked at a considerable forecast?

DR. GEHRING: We have not.

DR. LASSITER: You have here a possible form that the vinyl chloride might take in its alternate pathway. That is this detoxification of vinyl chloride.

Has this been demonstrated in people to occur?

DR. GEHRING: No, it has not been. We intend to pursue that, but we have not.

We have to make some initial hypothesis and then define the boundaries of our present conception, sir.

DR. LASSITER: On page 19 of your testimony, the last sentence says: In metabolizing vinyl chloride formed only via pathways, may constitute the ultimate toxicin and carcinogen.

Now, you have partially defined ultimate pathway comes in higher pathways under your studies, under carcinogens, about 200.

DR. GEHRING: About 220.

DR. LASSITER: Since, in this case, you would only have the metabolites which would be carcinogenic, supposedly formed above these areas, how do you recognize this up to 50 pm would be with your primary pathway?

DR. GEHRING: In Dr. Maltoni's data, they have now recently come up with an incident of tumors, I believe, as stated. He has changed this a couple of times. The New York Academy of Science and one after 135 weeks.

Well, the triangles, as I placed them into the slot and, if true, the cases I know, being a biochemist, that the other pathway still lets a few things through, as I tried to point out in that slide, so that is one possibility.

Of course, there are a host of other possibilities. There are different conditions in his laboratory, different rather than ours, and you could go on and on.

I think I feel that it is important to recognize that, in fact, I would like to show an additional slide, if I could, because when I was in New York in March of this year, at Dr. Selikoff's request, Dr. Maltoni was there, and I got his data to that date, and it showed a threshold.

Now, since this, this has changed.

(Showing slide)

What I have plotted there, this is a long probability plot of the data which Dr. Maltoni generously gave to us at that meeting, and you can see that about 250 parts greater pm.

The line was very great. In fact, the line I have drawn by inspection through the 3 points, from 250, 500 and 25, did not take into account the previous points.

Well, this predicted a level or an incident of cancer of about 8%, 50 ppm and there were none.

Now, the difficulty is, Dr. Maltoni's data have changed, so at 50 it is a little bit up higher.

On the other hand, it must also be pointed out, as indicated by Dr. Maltoni, at the New York Academy of Science, that 250 ppm and 500 ppm. He has a greater incidence now.

If I recall his figure right, and don't press me on this, I can't absolutely state it, but I think he said 16 out of 16 animals with tumors at 250 ppm. So, you are going to project that whole curve upward.

DR. LASSITER: Okay, thank you.

Can we have the lights again, please?

You mentioned the fact that there is a possible carcinogenic effect of vinyl chloride, in which vinyl chloride may be initiated or preparing a body site for the action of some other substance which actually would be the carcinogen.

How do you explain this in light of the animals studies in which exposure occurred only to vinyl chlorde?

DR. GEHRING: I am sorry, I do not believe I made that statement.

DR. LASSITER: You mentioned reduction in the non-protein, self-hydro content of the liver in animals exposed to vinyl chloride may constitute predisposition of toxiccity and carcinogenic contaminated by other materials.

DR. GEHRING: Okay, I understand now.

That is one potential mechanism, yes. If you will recall in the literature, the administration of methioline in animals subsequently exposed, or concurrently exposed, to radiation, trimethalyne and other agents, I believe, the Millers have even shown this with 2AAF; does the administration of these materials protects against the carcinogenic effect of these other materials.

A reasonable hypothesis is that those nice little self-hydro containing fragments found in a system laying around the liver may be the main purpose; that they are a protective mechanism, and we, during the notable process of metabolism, etcetera, produced many electro-filic materials and other materials which these could serve to sop up and essentially in the polimer chemist terminology, could be a chainn-stopper, or whatever.

This is a potential, again, a preconception, a hypothesis, which we somewhat negated by findint there was an adaptation.

DR. LASSITER: What you are saying is that these materials which would be carcinogenic, would already have to

be in people, and not something they would be simultaneously exposed to.

DR. GEHRING: That is correct. They could either be ionized in radiation.

DR. LASSITER: But you have controlled animal studies in vinyl chloride which was the insult.

DR. GEHRING: That is correct.

DR. LASSITER: That is all I have.

There is one point of clarification, Doctor.

MR. KLINE: Doctor, I wasn't here. Did you cover the Midland Plant in your study?

DR. HOLDER: Yes, the Midland Plant.

MR. KLINE: Nothing further.

JUDGE MYATT: Any questions from the audience?

Mr. Samuels, we have a new reporter. Give your name.

MR. SAMUELS: I am Sheldon Samuels, Industrial Union Department.

Dr. Gehring, DR. GEHRING: Was there some reason why you didn't test animals below 50 ppm?

DR. GEHRING: Yes, sir, there was. We do intend to do this in the future when we have the fourteen labeled vinyl chloride.

Unfortunately, the sensitivity of our instrumentation, which was the infra-red, somewhat limited us to how low we could go, because it is true we can pick up lower concentrations

initially, but we need to get enough of a duration over which that slope would drop to assure we were really getting that slope.

MR. SAMUELS: Very good. I understand that.

Now, you talked about a physiological threshold which you feel your date might demonstrate, is that right?

DR. GEHRING: Yes.

MR. SAMUELS: Now, would a physiological threshold for this strain of animals which you used, be different even for the same species for another strain of animals?

DR. GEHRING: Yes, it can be different.

MR. SAMUELS: Would the physiological threshold vary with change of diet for the animals?

DR. GEHRING: This is likely. It can occur.

MR. SAMUELS: And perhaps also could cause an insult; more than one environmental factor that is also suspected to be carcinogenic.

Did that affect the physiological threshold for this carcinogenic?

DR. GEHRING: It can affect it.

MR. SAMUELS: Doesn't that mean, then, that we are talking about a spectrum of values that is very difficult to determine when you translate it to humans with the varied genetic background, diet, other insults, from the community in the plant?

DR. GEHRING: That is always true. When you translate from human to human, that is true.

MR. SAMUELS: Right. Now, that being so, when you try to translate a physiological threshold to a standard for purposes of enforcement, isn't it necessary to have a margin of safety?

DR. GEHRING: Yes, it is. You have to be very careful here.

We are not in this case faced with a new compound for which we do not have human experience and human data.

MR. SAMUELS: I realize that.

DR. GEHRING: Where exactly that threshold lies for man, obviously has not been determined.

MR. SAMUELS: Okay, but still as a matter of enforcement you expect the Government to provide a margin of safety in translating data, physiological, epidemological, histological, you name it.

Would you expect that to occur? Would there be a margin?

DR. GEHRING: Again, when you talk about margin of safety, I am not disagreeing with that at all, when you have a new, unique compound.

I think the Government in this case must have considered the animal data, not isolated, but together with the human data.

MR. SAMUELS: I would certainly agree with that.

Now, we hear about margins of safety, how they are calculated.

What in Food and Drug, for example is the accepted margin of safety?

I know the Society of Toxicologists argue about this all the time and I think we ought to get it on the record.

DR. GEHRING: It varies with differer[illegible]rials and I don't know.

MR. SAMUELS: A whole range of spectrum?

DR. GEHRING: It is one 100th.

MR. SAMUELS: So, a margin of safety that might be applicable to humans might be one 100th there of the physilogical level after taking into account the epiodemological data, etcetera.

DR. GEHRING: You don't infer I agree with theFood and Drug Administration.

I think that, again, has to be based upon the human experience.

For example, pigs given the same dose of penicilin as man is given, all die.

So, what we infer by that we all need a hundred fold margin of safety when you give it to man.

I think you have to balance all of these things out of rule of reason again.

MR. SAMUELS: Whenever the rule is reasonable.

DR. GEHRING: I am not trying to evade your question.

MR. SAMUELS: I understand.

DR. GEHRING: Take any isolated incident and say, okay, this threshold is great and look at that in an isolated fashion, it is not consistent with rule of reason.

MR. SAMUELS: I agree and that is why my next question is for Dr. Cooke.

Dr. Cooke, have you matched the clinical result with the actual sampling data of the work involved?

That is to say I don't know how complete the data is, but I suppose somewhere, some place the actual exposure record of workers exists or did exist, and they could be matched with that worker's clinical effects.

DR. COOKE: For the specific --

MR. SAMUELS: For the specific worker.

DR. COOKE: That is how we compiled the results.

MR. SAMUELS: Okay, now, you were here, I hope, when Dr. Selikoff noted that at least for one chemical, I don't have his testimony in front of me, that there was some excess morbidity.

I don't remember exactly, but I think he said the extent of two standard deviations.

Do you remember that?

DR. COOKE: I don't have his testimony here either.

The figure that I recall is that he noted a number of "abnormal cases."

I don't know what his definition of "abnormal" is.

He mentioned later in his testimony the normal upper limit for his laboratory was 1.1.

Our per limit differs. Consequently, if we did the same test on the same individuals, we would come up with different results.

MR. SAMUELS: I see. Then that would certainly explain, in fact, the difference between your results and his, if there is, indeed, a difference. I am not sure there is.

DR. COOKE: I don't really know.

I would like to see his testimony.

I would like to see his protocol and look at this some more.

MR. SAMUELS: But, one possible difference is laboratory variation.

DR. COOKE: That is one possibility.

MR. SAMUELS: In your study, you looked at current employees, employees who are now on the payroll or were before the strike.

DR. COOKE: Employees between the period 1967 and March, 1974.

MR.SAMUELS: But these were employees, all employees between that period of time, including those who left the

company?

DR. COOKE: By definition, what we were looking for, in other words, are health surveillance data for our multi-phase screening result.

Multi-screening procedures was only available between 1967 and 1972, after employees, and that is the data that we evaluated.

MR. SAMUELS: I see. And so that there wasn't any attempt, let us say, to go into the community and find workers who had not had the benefit of screening. Screen them and match their results with their exposure record.

DR. COOKE: Not in this particular study, no.

MR. SAMUELS: Okay, Dr. Holder, if I may ask you some questions. Not having had the benefit of having a copy of your very excellent paper, I will have to go by memory.

Did you say that there were observed effects, or no effects, in the lower exposure cohort?

DR. HOLDER: In the lower exposure group, there were no adverse effects compared to the expected level of diseases in that group.

MR. SAMUELS: Were these observed or are you simply saying there would be none?

DR. HOLDER: No. In any population here today, there is disease.

We could compare this against the normal expected

rate and in the lower group, I am just picking the top slide off here and that's due to malignant mioplasms, one in the lower exposure group we observed for and we expected 4.5.

MR. SAMUELS: I understood that.

What I am really trying to lead you to examine is whether this negative result gives us the negative conclusion that there could be no effects there, no adverse effects.

DR. HOLDER: Adverse effects that would be related to the man's work enfironment?

MR. SAMUELS: Yes.

DR. HOLDER: No adverse effects related to the man's work environment in the lower exposure group.

MR. SAMUELS: I understand that. I am using the word "could."

DR. HOLDER: I don't understand your question.

MR. SAMUELS: Could there be effects, in other words? Is there a statistical possibility of effects that perhaps you didn't pick up? For example, it wasn't clear to me, but you didn't match these death certificates with any kind of physiological examination of autopsy material, etcetera.

DR. HOLDER: I think I mentioned we viewed autopsy material in 40% of our population.

MR. SAMUELS: You did do it?

DR. HOLDER: Yes, the other 60%, the exact figure, if you are interested, or the autopsy data is available if you

are interested. The other 60%, of course, were death certificates and obviously there is no pathological review review specifically of a death certificate. That goes without saying.

MR. SAMUELS: Okay, now, the population, you went through the list of all workers who had been employed in this part of the plant or is it the whole plant?

DR. HOLDER: No.

MR. SAMUELS: Just part of it?

DR. HOLDER: The study was the people who had been exposed between the years 1942 and 1960, plus.

They must have had exposure during those years to have qualified to vinyl chloride.

MR. SAMUELS: Wether or not they were in the retirement plan, whether or not they were still employed?

DR. HOLDER: That is right.

MR. SAMUELS: Very good.

DR. HOLDER: And I think I cited that we have not been able to follow up on roughly 17 and we are in the process of obtaining 16. I am sorry that was not available today, but the wheels of the universe unfold slowly.

MR. SAMUELS: I think in a short period of time, you did very well.

Doctor, did you examine patterns of rotation among the workers from job classification to job classification from

one part of the plant to another?

In other words, is there a possibility of unexposure here where a worker would not remain very long in one kind of a job, for example?

DR. HOLDER: If he remained -- and I might ask Mr. Otten to correct me on this -- if he remained more than a month in a high exposure place, we were extremely critical of those individuals, possibly too critical of those individuals and who had any remote possibility of a high exposure, and I think in crystallizing my own work, we may have been too critical of this, but so be it. That is our methodology we did use.

MR. SAMUELS: Thank you very much.

JUDGE MATT: Are there any other questions?

MISS HRICKO: Andrea Hricko from the health research group.

First, for Dr. Cooke.

How many employees at DOW have worked in vinyl chloride and PVC production since 1939, when PVC and VC were first defined?

DR. COOKE: I think Dr. Holder defined that population so you may want to direct the question to him.

DR. HOLDER: If you want to include those who recently, within the last five or ten years, have been working since 1960, I believe, the population gets up into 700. That is

not a solid figure. I can give you that data later.

Mr. Otten, do you have that?

MR. OTTEN: No.

DR. HOLDER: It can be obtained. As a rough ball-park figure, I would say 700 or 750.

MISS HRICKO: The people in your study, Dr. Cooke, the 338 employees you studied. Were all of those employees who were alive and who were employed during 1967 and 1974 at DOW Chemical, is that correct?

DR. COOKE: The 335?

MISS HRICKO: The 335.

DR. COOKE: The 335 employees were the ones by definition who we had self-surveillance data on and we only did the procedure from 1967 to 1974, so, consequently for them to go through the trailer they had to be alive during that period.

MISS HRICKO: Just to clarify one other thing. If a worker started working in vinyl chloride at DOW in, say, 1942, they were 20 years to exposure and retired in 1962, would he or she be included in the study?

DR. COOKE: He would not have gone between the health inventory trailer between 1962 and 1974, no.

MISS HRICKO: Since Dr. Holder's studies are basically a mortality study on employees who have retired from the company and are alive, they would not be included in

either study, is that correct?

DR. HOLDER: May I answer that? You say have not been included?

We are, and I think we recognize this concern over our retired employees and we are not actively starting a program for all retired employees, whatever their status may be or their location, they will be invited to participate in a health surveillance program at any Dow location throughout the country.

The past study knows these people were not included.

At present, they will be.

MISS HRICKO: I have a couple of questions for Dr. Holder.

In what process do workers at Dow get exposed to arsenical materials?

DR. HOLDER: Possibly, forgive me, as I am not a chemist. We were in the process of making arsenic materials to be used in the agricultural chemical insecticide division. This goes back to the early years of 1919. It dated over into the 1940's and we did not produce this. I do not think we have since 1956.

This will all appear in the Archives and Environmental Health in detail, I believe, in the next month or two.

I do have a copy if it is appropriate for the record, and I can give them a copy of this free publication.

MISS HRICKO: That report will deal with the workers

exposed to arsenic?

DR. HOLDER: Arsenicals only. It has no relationship to vinyl chloride.

MISS HRICKO: What percent of the total workers in your study were exposed to arsenic and vinyl chloride?

Was that in your report?

I don't have a copy.

If it is in the report, it is all right.

DR. HOLDER: We have had 72. I can go and turn back to my very capable biostatistician, Mr. Otten, but I believe we had 72 of the 594 who had complained of exposures.

MISS HRICKO: Can you tell me if those workers who were exposed to arsenic were also workers who had been exposed to the longer period of time to vinyl chloride?

Has that association been made?

DR. HOLDER: No, I don't believe these are our long exposures to vinyl chloride. I can give you the exposures, the deaths.

MISS HRICKO: That is what I would like, the exposures.

If you could submit it for the record, the exposures, that would be fine.

DR. HOLDER: This is in the record.

MISS HRICKO: In other words those deaths from malignancies, exposure to both?

DR. HOLDER: This is in the record.

Would you like me to read it?

MISS HRICKO: No, as long as it is in the record.

On the basis of your study, do you think that vinyl chloride may be a cause of multiple site cancers in man?

DR. HOLDER: Yes. Our study indicates that there is an increase in malignancy rate that is associated with two things, high exposure, duration and latency.

MISS HRICKO: Thank you. How long do you normally save medical records?

DR. HOLDER: Let me just continue this.

I cannot say that it is a carcinogenic, multiple sites, because of the posture I discuss, the imminent suppression. This is a small study and these were just -- I hate to use the word because I somewhat was chastized by the word in my talk, these were clinical observations.

MISS HRICKO: How long do you normally save medical records at your PVC or VC plant?

DR. HOLDER: We save all medical records until death of the employee, possibly 7 or 10 years following death, and of those people who have been released from the plant, we are keeping them -- yes, it has been 25 years after release.

In other words, if you leave Dow today, I will keep your record 25 years.

If you retire, I will keep it until you expire and

then I will keep it at least for 7 years following this.

MISS HRICKO: Thank you.

Since the latency period for angiosarcoma in liver in man was found to range from 11 to 30 years, would you recommend a change in the OSHA standards for keeping medical records for only 20 years?

DR. HOLDER: I think that is adequate. You see, everything is relative. I think it is an adequate proposal.

MISS HRICKO: You think the 20 years is adequate?

DR. HOLDER: We would like a little bit longer for a variety of reasons, but I think the present proposal is adequate.

MISS HRICKO: Could you, perhaps, explain why you think that is adequate if people have developed cancer 30 years after exposure, how maintaining the records for only 20 years would help develop any data?

DR. HOLDER: I think you have to react to the majority here and I think the majority can agree to a 20 year latency period is accepted latency period. There are exceptions again in the bell curve.

All I can do is tell you what we do and I don't feel I am in a position to dictate to OSHA.

As I say, I think it is acceptable.

We feel we should keep it longer.

Maybe I haven't answered your question.

MISS HRICKO: Would you submit for the record copies of Dow's medical surveillance and protocols and any changes in those protocols, revisions that have taken place since 1961?

DR. HOLDER: Yes, I will be glad to do so.

I think you have to understand our program. We have been having -- and this goes back to the statement that we have been conducting medical surveillance on our people, all of our people, our chemical workers, by the way, and the vinyl chloride has not been unique, and we conduct the same type of surveillance on all of our people, and we have been maintaining our mortality studies on all people.

Almost every year, as our technology expands, we change or enlarge our medical surveillance, so your question is a little bit difficult.

If you could be a little more specific, I will be glad to provide you with all the records.

MISS HRICKO: In other words, some of the countries have had liver function tests dating back to early 1960 for workers exposed to vinyl chloride and these medical surveillance protocols have evolved in they changed as more scientific data has become available.

DR. HOLDER: Ours have also.

MISS HRICKO: Could you submit for the workers exposed

to vinyl chloride the changes that have taken place over the years?

DR. HOLDER: We used to do the VKP years ago. We are no longer doing this. I will try to put something together for you because it has been in a continual state of flux and this is the point I want to make. It is kind of hard to say.

We will try to put something together.

MISS HRICKO: I have one question for, is it Mr.Rogers?

DR. DANIEL: It is Daniel.

MISS HRICKO: Would Dow have to make any changes in its current operations to be in operation with the SPI recommended standard?

DR. DANIEL: Repeat your question.

MISS HRICKO: Would Dow have to make any changes in its current operations to be in compliance with the SPI recommended standards?

DR. DANIEL: I think fromthe data we presented today it is obvious that we still have problem areas, that we will have to make changes, find some way to cope with the levels that people are exposed to from time to time.

MISS HRICKO: Since Dow's operating level has generally been around the 10 ppm level, do you think there would have to be significant change of 10 ppm, the time weighted average?

DR. DANIEL: Well, once again, we showed two to three worker populations that have very definite problems and so, obviously to meet the 10 ppm, we would have to continue our efforts to develop techniques to consistantly reduce their exposures.

MISS HRICKO: Thank you.

My other questions are for Dr. Rowe.

DR. HOLDER: Can I expand just a minute on a question, and, Dr. Rowe, correct me on one statement which was very appropriate and I am sorry, maybe in the dialogue here, I missed this.

We do not conduct examinations on all of our employees.

We conduct examination on all Dow employees who will vonuntarily submit.

We have made available for years periodic health examinations and one of our biggest problems is getting over this 80% acceptance. It is the 20% that refuse.

How do we do this?

If anybody would help us, we would be very appreciative. Yes, there is 80% that accepts it.

MISS HRICKO: Thank you for the clarification.

Dr. Rowe, these questions will be directed to the development of monitoring and medical surveillance and protocols which the development you testified takes place at Dow.

First, did Dow revise its medical surveillance for PPM level as a result of the 1970-older data?

MR. CONELLY: I object to this. This is the same questioning that was ruled improper.

JUDGE MYATT: May I hear the objection before I hear you respond?

MR. CONNELLY: I don't think it is appropriate to deal with anything other than what the final standard is going to be and the information that deals with that, and something that may have taken place as a result of someone else's data five or ten years ago is of no relevance to this hearing.

MISS HRICKO: May I explain?

JUDGE MYATT: Please.

MISS HRICKO: One of the major things we are looking at today with regard to the standards, the Secretary will have to evaluate the weight to attach to particular scientific evidence that has become available in the last few years.

Now, particular employees have done their own research and they have also studied research.

Studies have been done in foreign countries with regard to the carcinogenity of vinyl chloride.

It is important to understand how the data or changed their threshold values internally, and it is important so the Department of Labor can attach the weight of the scienfific

evidence.

JUDGE MYATT: Well, I will overrule your objection. You may answer the question.

DR. DOWE: I am sorry, I do not believe I can answer the changes in the medical surveillance program.

I would defer to Dr. Holder, whose responsibility that is.

DR. HOLDER: No, we have not.

We have felt we have had a very inclusive medical surveillance for all of our chemical workers, which included vinyl chloride.

We have made no changes in our medical surveillance program.

MISS HRICKO: And, again, that would be in 1973 when Dow received information about the Maltoni data?

DR. HOLDER: This is in 1973.

We were, unfortunately, interrupted in our medical surveillance in our 1974 screening of our population because of work stoppage or strikes, whichever term you wish to use.

The program we were using at that time is a standard protocol for all medical workers which did involve extensive screening of the liver, etcetera, and the same thing we did basically, in 1973, no changes were instigated because of Maltoni, etcetera.

Dr. Cooke, would you agree on this? I am talking

his area now.

MISS HRICKO: On the basis of what scientific data did Dow advise its vinyl chloride customers in May of 1973 against using vinyl chloride as an aerosol propellant for consumer products?

DR. HOLDER: Dr. Rowe, do you wish to comment on that?

MISS HRICKO: I would like to know the scientific data Dow relied on to advise its customers not to use vinyl chloride as an aerosol propellant?

DR. ROWE: We had heard at that time of Professor Maltoni's preliminary results. We did not have the details of what he had at that time.

We did not know what the significance of it was, but it just seemed prudent not to continue that in which a very trivial part, that is a very trivial part of our business anyway, and it seemed prudent not to do that.

MISS HRICKO: You say it was a report in the Maltoni data but you did not have the data at that time.

Isn't it true someone advised Dr. Maltoni in January of 1973 to obtain that data?

DR. ROWE: We had some observations. We did not have the whole data.

The only reason that we were ever -- one of our people went over, it was simply to see what kind of data that

might be available, particularly from the standpoint of pathology.

MISS HRICKO: But it was then on the basis of the preliminary results that you did advise against using vinyl chloride in consumer products?

DR. ROWE: Yes.

MISS HRICKO: Whose responsibility is it at Dow to inform the medical directors and examining physicians of plants of toxicological data that shows the chemical may be hazardous?

DR. ROWE: Would you please repeat that?

MISS HRICKO: Whose responsibility is it at Dow if new data is developed, new toxicological data showing a chemical may be hazardous to workers exposed to the chemical? Whose responsibility is it to notify the examining physicians at thevarious Dow plants?

DR. ROWE: I think that is probably in your field, Dr. Holder.

DR. HOLDER: Let me go back to the statement I made before.

I think you have to understand the way Dow is functioning. I think we all believe that health is a multi-disciplined direction. Our toxicological, hygiene and medical people meet twice a month, basically, to review all of our combined information and share back and forth, as to problems, developments and technologies, and so forth.

Basically, it would be the corporate or U.S., these are toxicological terms, specifically, Dr. Gordon's responsibility to inform other major divisions who probably would be in these meetings as to any new developments in toxicology.

MISS HRICKO: Was information on the Maltoni results showing cancer of the liver given in early 1973 to plant physicians who might be examining workers with liver disease?

DR. HOLDER: I can't recall it right.

Dr. Burton is not here. I am sure the information could be made available for the record.

As this information became public, it was most certainly conveyed to all of our smaller Plants.

Again, I am speaking for him, and so I have to qualify my statement.

MISS HRICKO: Was this information given to Dow employees in early 1973 to the workers?

MR. CONNELLY: Again, I object.

JUDGE MYATT: I agree with you.

MISS HRICKO: Can I explain?

JUDGE MYATT: I can't talk over both of you and I don't intend to.

I don't see how this is going to help anybody set a standard, Miss Hricko.

MR. CONNELLY: May I explain my objection first?

JUDGE MYATT: No, I don't want to hear your objection.

I object to this question too.

MISS HRICKO: May i explain my question?

In the Standards section, 1910.93(q,j) the proposed OSHA standards of vinyl chloride there is a section on training workers about the toxicity of vinyl chloride for the Secretary to make a decision as to whether that should be a mandatory program.

I think that he needs to have some idea as to what types of information companies are voluntarily giving their workers about exposure to vinyl chloride.

JUDGE MYATT: Wouldn't a better question be whether or not they do give out information, and if so, in what form?

MISS HRICKO: Maybe I can rephrase my question.

MYDGE MYATT: Please do. I am getting irritable and do it to please me.

MISS HRICKO: Has Dow given out any information to its employees, prior to January 1974, when there was experimental data available, and after the B.F. Goodrich data became available in January of 1974; were the workers notified of those results?

MR. CONNELLY: Your Honor, I would like to object and give my reasons.

A VOICE FROM THE FLOOR: I object to this person representing every person that get's up there.

JUDGE MYATT: And I object to both of you, right now. Sit down, both of you.

Answer the question.

DR. HOLDER: I hope I answer it correctly, but let me be very frank about it. Our posture is to inform all of our employees of all of the hazards that they are working with.

Now, to the best of my recollection, in the summer -- and I could be wrong on this -- in the summer of 1973, I believe we had some extensive sessions with our employees regarding the animal data experiments that were publicized.

We told the people at that time that we did have information that would lead us to believe that the materials they were working with were carcinogenic in animals.

I believe if I can have a nod from the gentleman out there -- yes, all right.

MISS HRICKO: Thank you, very much. I have one further question.

Dr. Rowe, you stated that cancer was "surrendipiously" discovered in Dr. Viola's experiments since he was looking at the cause -- well, when Dow introduces new chemicals there is a test for carcinogenocy?

DR. ROWE: The capacity to do that is simply not available.

MISS HRICKO: Then, has vinyl chloride ever been tested by Dow specifically for its carcinogenic effects?

DR. ROWE: No, ma'am.

MISS HRICKO: Thank you.

JUDGE MATT: Any other questions?

Before you ask your question, identify yourself.

MR. HECKMAN: H. Heckman, General Counsel for the Plastics Industry.

Dr. Holder, you are not opposed to the FMI proposal that records be kept for 30 years, are you?

DR. HOLDER: No.

MR. HECKMAN: I just wanted to get the record clear on that one.

Dr. Cooke, with respect to your question of a moment ago, about your data with respect to Dr. Selikoff's, and I indicated this was unclear to me, so any way you can say it that will clear it up will be fine. If you saw a certain level, I believe it was of the Billy Rubin, or one of those tests, you would not consider it abnormal, whereas he would. That is because you use different controls, isn't it, not because you would differ with the same data?

I think I am confused about this. I just wanted the record to be clear.

DR. COOKE: We usually use, or look at data and compare this to the standard of normal for a normal population or acceptable clinical normals, and for instance the upper limit to the -- well, in his laboratory, he has defined the upper

limit as normal, as 1.1, apparently, from the discussion in his data.

Does that answer the question?

MR. HECKMAN: I think it does.

You use different starting points, is what you are saying in effect?

DR. COOKE: Different benchmarks, right.

MR. HECKMAN: That is fine. That is perfectly safe.

Okay, Dr. Rowe, I have a couple of questions for you.

Is it true that Dow no longer produces polyvinyl chloride resin, per se?

DR. ROWE: That is correct.

MR. HECKMAN: When did you discontinue producing polyvinyl chloride resin, as such?

DR. ROWE: In, or around, 1969.

MR. HECKMAN: Was that because it was more difficult to control the emission or leakage, or what have you, of vinyl chloride monimer from polychloride in polyvinyl chloride path in what I will call polyvinyl chloride plants?

DR. ROWE: It is my understanding that is true. I have no first hand knowledge of the mechanics of this, but this is what our people tell me.

MR. HECKMAN: How long would you say it has taken Dow to reach its present level of exposure, by and large?

DR. ROWE: Well, we started a very positive approach

to reduce exposure to vinyl chloride in about 1960.

That would be 14 years.

MR. HECKMAN: Thank you.

Dr. Gehring, I have one question of you, I believe.

Dr. Gehring, the other day you questioned someone of industrial biotest about the incidence of mortality.

Since there is some question about the sensitivity and, therefore, the relevancy of using data obtained to assess the hazard to man, would you expand further on the significance of your question, and the subsequent answer you got from Dr. Kapinger?

DR. GEHRING: Subsequent to that session, I did get the most recent data from industrial biotesting, and the incident in mortalities after 9 months of exposure are the following -- control, 16%, 50% per million, 31%, 500 ppm, 47% and 2500 ppm, 66%.

In other words, the incidence of mortality was two-fold greater than controls in those exposed to 50 ppm, three-fold greater than those 500 ppm, and four parts greater than these exposed to 2500 ppm.

This becomes very important when you start projecting animal data to assess or evaluate what the risk to man might be.

We don't, for example, have a two-fold increase in mortality in man exposed to 50 ppm or three-fold increase in

those that have been exposed to 200 or greater, and I feel that we would certainly have picked these up.

Indeed, even if Maltoni's study is only level, I believe that did not cause an increase in mortality; it was either 250 or 500 ppm. This is very important and it is to the extent that -- in the national interest to enter a new protocol that they issued on June 17, 1974, which I have a copy here, and I can state, in essence, and I can read the exact statement, but in doing carcinogenic screening for evaluation bioassays, they say no dose level shall be used that causes marked pharmalogical or toxicological activity, and mortality of course, is rather a toxic activity.

In essence, the mice are truly more sensitive, I believe, to the production of human angiosarcoma, but they are more susceptible, and, really, I feel, the test is negated for projection to man.

MR. HECKMAN: Do I also understand you to say in answer to a question that was posed, something to the effect the Maltoni data could be, when read to man, there is a no-effect level of taking your work into account, or possibly no effect levels, I should say, at or around 50 ppm?

DR. GEHRING: I avoid the terminology, "no effect level," rigorously.

MR. HECKMAN: Okay.

DR. GEHRING: Because, as you know, our technology

inyl
de

increases and what was no effect a few years ago -- yes, I will say no discernible effect, at least, there.

There is a discontinuity in his normal population. If that were a normal population, it would be rather hard to anticipate and explain why the projected incidence of tumors wasn't true in 50 ppm, although, as I qualified this, that was Maltoni's data up to that point in time.

This is not the case any more.

tape9

MR. HECKMAN: Well, then finally, the last question, do you feel that the PSI proposal in principle, not word for word, is reasonable taking into account the state of the art in the industry in general, including the poly vinyl chloride resin industry as distinguished from the poly PV industry in light of your evaluation of the safety data at hand and the feasibility information you have heard in the past few days?

Want me to repeat the question?

DR. GEHRING: Would you, please?

MR. HECKMAN: With the co-polymer, if I can refer to it as the co-polymer it would be easier.

Do you feel that the SPI proposal is reasonable taking into account the state of the art and the general industry and your evaluation of the safety data at hand at the moment?

DR. GEHRING: To say this a bit differently, and I suspect this is the answer, there are numerous things involved in setting any level, worker jobs, foreign trade, technology for a particular plant, and so on.

In my opinion, if I examine the toxicological data available as well as the human data which has been shown here there is not any discernible indication, or any, at least, specific indication that 50 parts per million, for example, constitutes an unreasonable risk.

That is not to say that if, being a toxicologist,

I want people to do whatever they can to lower the risk, so I think the thing is that if you have the technology to reduce that level and to get down further, that is only prudent, and only makes good sense.

The part that I have in it is to define what area is a reasonable risk.

MR. HECKMAN: I think that is adequate.

Thank you.

MR. KLINE: Excuse me, Your Honor, if I might make a request that Dr. Gehring provide for the Department of Labor the latest bio-test result that he has in his possession.

DR. GEHRING: I am sure this will be the case. I am sure the MCA will give those, but I do not feel free to give them.

MR. KLINE: If I may ask a question, did bio-test indicate you were not to give them to us?

DR. GEHRING: No, they did not.

MR. KLINE: Is there any reason that you can think of that you should not?

DR. GEHRING: No, I am somewhat apprehensive about taking the liberty with someone else's information.

I am sure they will.

JUDGE MYATT: If you can provide them, fine. If not, I am sure the Department can get them.

DR. GEHRING: I am absolutely sure.

MR. CONNELLY: My name is Walter B. Connelly, Jr., with Firestone Tire and Rubber.

Could I state that I do not represent Dow Chemical for the record.

I wonder if Dr. Holder could comment on whether or not there is any particular significance, or any particular difference between the effect, the medical effect, upon an individual, say exposed to poly vinyl chloride between a level of say 15 parts per million and the effect of an exposure of, say 25 parts per million?

DR. HOLDER: Would you reword the question?

Did you say poly?

MR. CONNELLY: PCM.

DR. HOLDER: A great difference.

MR. CONNELLY: I guess I have it on the brain.

I base the question on the supposition that you have, that there is no effect below what you discern, below 200 ppm.

DR. HOLDER: I will try to answer.

That is a difficult question, and I would ask my colleague, Dr. Cook to support me, or to refute me on this.

In our experience we have not been able to ascertain any difference in medical evaluation of individuals exposed to 15 or 20.

There is nothing in our expertise that draws a

line that fine.

Dr. Cook?

DR. COOK: I agree.

MR. CONNELLY: So to perhaps paraphrase that last statement, in the opinion of your company, and yourselves for all practical purposes then, it will be no difference in the effect between 15 and 25 ppm?

DR. HOLDER: All I can say is our studies will be conducted, and if I had a mass of people, or significant, I will strike the word "significant," if I had a reasonable number of people exposed to 15, and a reasonable number exposed to 25, and I can do good eipdemiologic studies on both, I might have an answer for you.

But I am sorry, with our studies and techniques we use I cannot answer the question, or see any discernible difference.

MR. CONNELLY: It is your opinion as of this juncture that there is no practical difference?

DR. HOLDER: This is my opinion from our experience, that there is no practical difference.

MR. CONNELLY: I am not sure if you have answered this question, so maybe have you been able to discern any differences in the problems of exposure between plants, say in the northern part of the country versus the southern part of the country which are general open air plants in terms of the

exposure levels and the problems of changing or renovating the older plants in the north in comparison with the south?

DR. HOLDER: I would like to ask Dr. Langer, who is in the south, and if he can answer that.

DR. LANGER: Yes, sir, there is obviously a difference.

If you have an open air plant as you have in the south, especially on the Gulf Coast, with the prevailing wind of ten or 15 miles an hour, it is very easy to control your exposure levels in the plant like that versus a closed plant which you have in the north.

MR. CONNELLY: Is it safe to assume that it would cost more money to reduce the level of a plant in the north as compared to reducing an open air plant in the south?

DR. LANGER: Yes, if you have a closed plant in the north, when you start putting more ventilation through it in the winter time if you want a comfortable temperature, then you must heat the air you pull through, and the same way in the summer time.

If you have a closed plant you must provide more air conditioning than you would with the open air plant.

MR. CONNELLY: On the part of myself, and on behalf of Firestone, we would like to thank Dow Chemical for all the excellent work they have done in their presentation.

Thank you.

Ex 161 Attachment VII

ABSTRACT

LONG-TERM MORTALITY EXPERIENCE OF 594 EMPLOYEES EXPOSED TO VINYL CHLORIDE IN A CONTROLLED INDUSTRIAL ENVIRONMENT

Ott, M. G., Langner, R. R., Holder, B. B.

Vinyl chloride has been associated recently with findings of angiosarcoma in animals and man. The present study examines, through 1973, the mortality experience of individuals occupationally exposed to vinyl chloride. The cohort was established by identifying employees who worked in exposure areas between 1942 and 1960.

Workers chronically exposed to levels above 200 ppm TWA for at least one month demonstrated an apparent increase in overall malignancy rate. No adverse mortality effects were observed where exposures were controlled below 200 ppm TWA. No angiosarcoma was found and there were no deaths due to any liver malignancy.

Findings in this study support the need for further research on possible immunosuppressant or co-carcinogenic effects of vinyl chloride.

LONG-TERM MORTALITY EXPERIENCE OF 594 EMPLOYEES EXPOSED TO VINYL CHLORIDE IN A CONTROLLED INDUSTRIAL ENVIRONMENT

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LONG-TERM MORTALITY EXPERIENCE OF 594 EMPLOYEES EXPOSED TO VINYL CHLORIDE IN A CONTROLLED INDUSTRIAL ENVIRONMENT

Vinyl chloride has a 30 to 40 year history of industrial use. Until recently, it was thought to be a relatively benign material and, in fact, was once considered for use as a surgical anesthetic. Reports documenting anesthetic effects in animals and humans and liver injury in animals from chronic exposure were published in 1960-1963 by Mastromatteo et al,[1] Torkelson et al,[2] and Lester et al.[3]

A new clinical entity associated with vinyl chloride exposure, acro-osteolysis, was reported in the U.S. by Wilson et al in 1967.[4] This was elaborated by Cook et al,[5] Dodson et al,[6] and Dinman et al.[7]

In 1972, an environmental study of vinyl chloride workers by Kramer and Mutchler[8] revealed laboratory indications of liver disease in workers exposed to a time weighted average concentration for an eight hour day (TWA) of 300 ppm or above. Reports of other effects associated with exposure to high levels of vinyl chloride were summarized by Marstellar et al[9] in the European literature.

Neoplasia was first associated with vinyl chloride in 1971 by Viola et al.[10] Maltoni[11] later reported malignant changes in animals, including angiosarcoma of the liver. Creech and Johnson[12] supported this observation by their report of angiosarcoma of the liver in vinyl chloride workers. In May 1974, Tabershaw and Cooper[13] released their industry-wide epidemiological study of vinyl chloride workers that suggested increased numbers of malignant neoplasms at other body sites.

This paper summarizes the mortality experience of an industrial population exposed to vinyl chloride in an environment for which many years of

monitoring data are available. Many of the employees were also included in the Tabershaw and Cooper report; however, in the present study the mortality experience was combined with more definitive levels of exposure and followup of former company employees.

HISTORY

Research involving vinyl chloride started at this company location in the mid-1930's. In 1941, a small copolymer plant was constructed which employed four operators, two miller-packagers, one foreman and one superintendent. In the late 1940's, the plant capacity was enlarged and two assistant operators joined the work force. The copolymer plant continued to grow and other types of copolymer were developed, which resulted in a larger department with a new group of operating, clerical and supervisory personnel. A small production unit to produce vinyl chloride monomer and a copolymer semi-plant also were operated during this period.

Continued research resulted in a new outdoor homo-polymer (PVC) and copolymer unit being constructed in 1952. The rapid development of the market for PVC resin in the 1950's outstripped the new plant capacity. In response, PVC production was begun in a portion of a third copolymer unit which had previously used only limited quantities of vinyl chloride. Thus, besides the research efforts and monomer production, three polymer units were in operation. PVC was produced until 1969, when the decision was made to discontinue production of homo-polymer and use the facilities to modernize copolymer production. The modernization allowed the closing of the plant built in 1941.

INDUSTRIAL HYGIENE METHODS AND RESULTS

Initial measurements of the work environment began in 1959. At that time, it was the accepted practice to collect breathing zone samples by

adsorption on silica gel.[14] With this technique, the sample was burned in a furnace. The resulting chlorides were determined by the Volhard method and calculated as vinyl chloride. Since both homo-polymer and copolymer plants were operated, the breathing zone samples contained an undetermined quantity of other halogenated compounds and airborne halogens. Studies performed at a later date, using more sophisticated methods, verified that in most of the jobs 85% or more of the measured halide was vinyl chloride.

In 1959, a continuous conductivity analyzer was installed in the largest copolymer operation.[15] The unit consisted of a 6-point sequential sampler which drew air from predetermined fixed points through 5/16-inch I.D. Saran® tubing. Today, polypropylene tubing is used to replace the Saran® tubing. The fixed monitoring station can be as much as 200 feet away from the furnace unit. Filters or glass-wool plugs have been used to prevent bugs and large dust particles from entering the tube and restricting air flow.

The air is fed into a furnace and burned to chloride. Deionized water is used to scrub the furnace exit gas and the conductivity of the water is determined. As with prior conventional industrial hygiene sampling, all chlorides are burned and reported as vinyl chloride. Thus, the reported values are usually higher than the actual concentration, which provides an added safety factor when such an instrument is used to control exposures. The results are obtained every six minutes from each monitoring point and are printed onto a circular graph for employee observation. The monitoring instruments are equipped with both visual and audio alarms to alert the employees when the airborne level reaches a preset value. These monitoring devices can be connected to a computer for calculation of time weighted average concentrations by job classification and for data storage and retrieval.

Using similar sequential samplers, it has been possible to adapt infrared spectrometers for monitoring work areas.(17) In recent years, gas chromatography (GC) has been adapted to do similar monitoring. And, finally, the combination of GC and mass spectrometery has been used for more positive identification of the airborne material. The latter two systems have been more widely used to analyze either grab samples or carbon adsorption samples in personnel monitoring.

Surveys of the work environment were made during the period of 1950 through 1959. The results are presented in Table 1 for Production Unit I. The work areas in this unit included wet end and dry end operations, separated by a wall. Although the TWA estimates were well below 500 ppm, excursions up to 4000 ppm were documented in the wet end operations. The measured excursions agree with employee reports of dizziness experience on jobs involving loading and unloading reactors during this era. The mechanics operated in both parts of the plant and, due to the nature of their work, certainly experienced intermittent high exposures.

Industrial Hygiene surveys of the newer homo-polymer plant, Production Unit II, show there was an improvement in the operation, but exposures above 50 ppm did occur for several operations. See Table 2. Again, these results reflect the excursions that have been reported verbally by the employees.

The continuous monitor installed in Unit I in 1959 aided in detecting sources of exposure. About this time, toxicological data became available which indicated adverse effects in animals exposed to 500 ppm vinyl chloride.(2) As a result, a 50 ppm Dow Industrial Hygiene Guide was established for the work environment. Unit I improved their operations and, with few exceptions, were able to operate below the 50 ppm guideline. Table 3 presents these data. Although the TWA estimates were significantly reduced, excursions and peaks did continue to occur throughout the measuring period.

Table 4 presents a summary of industrial hygiene data for Production Unit II. Except for the coagulator operator, exposures were not reduced. This lack of improvement in contrast to Unit I reflects both the differences in product mix and the type of processes used. A continuous analyzer was installed in the outdoor plants in 1968. Homo-polymer manufacturing terminated in 1969. Redesign of the plant and changes in work practices have resulted in current TWA exposure levels approximating 10 ppm.

Employees in all units were also potentially exposed to varying lower levels of vinylidene chloride, methyl methacrylate, acrylonitrile, methacrylonitrile, catalysts, stabilizers, plasticizers, emulsifiers, suspending agents, and other additives.

METHODS OF MORTALITY ANALYSIS

The population of interest was defined as production employees who worked between 1942 and 1960 in areas with potential vinyl chloride exposure. The employees were identified from departmental census lists prepared in January of each year. Nearly all the men who worked at least one year, and about half the men who worked less than a year, were identified. The lists were reviewed over the specified years for five production units previously described: Unit I--Copolymer Plant, 1942-1960; Unit II--PVC and Copolymer Plant, 1953-1960; Unit III--Vinyl Chloride Monomer Plant, 1947-1954; Unit IV--Copolymer Semi-Plant, 1946-1955; and, Unit V--Vinyl Latexes and Polymer Plant, 1946-1960.

Exposure measurements were available for the two larger units (Unit I and Unit II), but not for the three smaller units. To investigate dose response relationships with respect to vinyl chloride, industrial hygiene data were reviewed for each job classification and each job was assigned an exposure level of low, intermediate, or high. The three categories were

defined primarily based on estimated time weighted average concentrations for an eight hour day. The low level was defined as TWA concentrations below 25 ppm vinyl chloride, the intermediate level was defined as 25 to 200 ppm, and the high level was defined as 200 to 300+ ppm. The high exposure level was also assigned to several jobs with time weighted average concentrations in the intermediate range where frequent unpredictable excursions above 2000 ppm were known to occur. Changes in exposure level category for a given job because of improved industrial hygiene practices were properly recognized.

Since insufficient data were available to determine TWA estimates for the three smaller units, a fourth category of indeterminate exposure was defined for individuals working in these areas. A subjective evaluation of the three units by industrial hygienists indicated that exposures were in the low to intermediate range, with occasional excursions to high levels.

Because of job mobility, many employees experienced exposures at more than one concentration level. Individuals in the study population were assigned to exposure groupings based on the highest exposure experienced for one or more months. This procedure insured that the lowest exposure group contained individuals experiencing only low exposure, while the higher exposure groups would include individuals with mixed high and low exposures. In the analysis, duration of exposure was separated into two categories: less-then-one-year and one-year-or-longer. The dichotomy was chosen because of the small number of individuals involved in the study. For the intermediate and high exposure groups, length of exposure at lower levels was not considered in assigning the individual to less-than-one-year or one-plus-years categories. Thus, an individual exposed at high levels for six months, and at lower levels for ten years, would be classified in the high category with less than one year of exposure at that level. This strategy

preserved the identity of the highest concentration level rather than that of the accumulative dosage. 1780

Previous studies at this company location have indicated that individuals who worked in an arsenicals production area prior to 1956 were liable to an excess cancer risk. A paper dealing with the mortality experience of the arsenicals production employees has been submitted for publication. There were 72 individuals in the present study who were exposed to both arsenicals and vinyl chloride. The mortality experience of the vinyl chloride cohort is summarized with the arsenicals employees included and excluded. The arsenicals employees have been excluded from the tables that deal with dose response relationships with respect to vinyl chloride.

The numbers of expected deaths were determined by summing the person years lived by employees over five year calendar periods, by ten year age groups. The numbers obtained were then multiplied by the appropriate U.S. white male mortality rates and accumulated. U.S. data for the years 1942, 1947, 1952, 1957, 1962 and 1967 were utilized, with projected rates for 1971.

Followup of employees who left the company was obtained through interviews, review of county and state records, and through the Social Security Administration.

The cause of death has not been obtained for one deceased former employee who had been exposed to vinyl chloride for only one month. The death has been included in the All Causes category throughout the paper, but was not apportioned to a particular cause of death category.

RESULTS

The vital and employment status of the total cohort of 594 employees are presented in Table 5, by level of highest exposure. Of the 148 former

employees, 124 were living, 23 were identified as deceased, and one individual known to have left the U.S. was not successfully traced. Eleven decedents and 74 persons still living were traced through interviews and county death records. Sixty-two former employees for whom the above procedures provided incomplete followup were submitted for Social Security checks. Twelve of these individuals were identified as deceased. The remaining 50 men in the Social Security check were assumed to be living.

Table 6 summarizes the mortality experience, by cause, of the total cohort population and of the population less those employees exposed to arsenic. Seven of ten deaths among the 72 individuals who worked with arsenicals were due to malignant neoplasms. Only 1.9 deaths due to malignant neoplasms were expected for this particular subgroup of employees. Case summaries for the seven deaths are shown in Table 7.

Observed deaths among vinyl chloride workers not exposed to arsenicals were 91 percent of the expected deaths, based on the U.S. white male population. The background mortality experience for general chemical production workers at this manufacturing location is 15 to 20 percent below the U.S. white male population. However, followup of former employees in the vinyl chloride cohort has been more extensive than for other employee groups.

The three deaths due to cirrhosis of the liver occurred among individuals who left the company and who were exposed to vinyl chloride for less than one year. One of these individuals was discharged in 1948 because of alcoholic intoxication. Total malignancies were less than expected, 13 versus 16.0, among employees exposed to vinyl chloride but not arsenicals. No deaths due to angiosarcoma or liver malignancies were observed, nor have these diagnoses appeared on the death certificates as secondary causes of death.

To investigate mortality in relation to intensity of exposure, observed and expected deaths were determined for each of the four exposure groupings. Table 8 shows length of employment in areas involving vinyl chloride exposure relative to level of exposure. Total length of exposure was less among the individuals in the low exposure group than among the other exposure groups. One hundred twenty seven employees in the low exposure group worked for less than one year in the production areas of interest. A probable explanation is that more entrance jobs were found in the dry end of the polymerization processes where exposures to vinyl chloride were low. Many of the employees who remained with the units and established seniority eventually worked in the higher exposure areas.

The distribution of the malignant neoplasms with respect to exposure levels suggests a possible dose response relationship, as seen from Table 9. Although the numbers of deaths were small and therefore were not tested for statistical significance, nine of the 13 malignancies were observed in the high exposure group.

The mortality experience 15+ years after initial exposure is examined in Table 10. Eight of nine malignancies in the high exposure group occurred among individuals 15+ years after initial exposure. On the other hand, only four malignancy deaths were observed among the remaining exposure groups, with just one of these deaths occurring 15+ years after first exposure. The expected numbers of deaths due to malignant neoplasms in the remaining exposure groups were 10.9 for total years and 6.0 for 15+ years after initial exposure.

Case summaries for the 13 deaths due to malignant neoplasms are shown in Table 11. Seven of the nine individuals in the high exposure group had worked for more than ten years in exposure areas. The remaining two individuals worked for five and nine years, respectively.

There were two deaths for which malignant neoplasms were recorded on the death certificate as secondary, rather than underlying, cause of death. In each case, the death was coded to the category Diseases of the Cardiovascular System. Table 12 summarizes the exposure history for these two decedents. Both worked for short periods of time in low exposure areas.

COMMENT

No adverse mortality effects were demonstrated in the lower exposure categories where levels of vinyl chloride were controlled below 200 ppm TWA. An increase in deaths due to malignant neoplasms was noted among employees in the highest exposure category.

Several case histories and other findings in this study give support to an immunosuppressant or co-carcinogenic effect of vinyl chloride exposure. Six supporting case histories, from Table 11, are cited below.

1. Case 13. Leukemia (acute granulocytic).

   In addition to prior vinyl chloride exposure, this individual worked in an area associated with benzene exposure during the last ten years of employment.

2. Case 11. Adenocarcinoma of the rectum.

   Employee's mother, two brothers, and one sister died of malignancies.

3. Cases 9, 10, 14, and 15.

   Of the four lung malignancies in the high exposure group three, and probably the fourth, had a history of cigarette smoking.

Other findings include seven malignancies in the group exposed to arsenic and vinyl chloride, as opposed to 1.9 expected.

Together, these observations indicate the possibility of immunosuppressant or co-carcinogenic effects. Fully recognizing the limited data, this posture is presented only to encourage further research.

The present paper has been directed to mortality experience. We are presently compiling the health surveillance information on our living population and will publish this information as soon as it is completed.

ACKNOWLEDGMENTS

We wish to thank the past and present Industrial Hygiene staff who were responsible for the environmental measurements on which this report is based. Special thanks to H. R. Hoyle who not only did the original survey work but, also, had the foresight to record and store all of the Industrial Hygiene reports for future use. Also, special thanks to E. J. Schneider who has had the perseverance to continue studying the work environment and aid supervision in their continued efforts to improve the work environment.

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Table 1. Summary of Vinyl Chloride Measurements, By Job Classification, in Production Unit I, 1950-1959.

Job Classification	TWA 8-Hour ppm By Volume
Dry End Operations	
Foreman	5
Shipping Clerk	5 - 10
Utility	5 - 10
Packer	5 - 10
Assistant Operator	5 - 10
Shift Miller	5 - 10
Wet End Operations*	
Foreman	10 - 50
Crew Leader	10 - 50
Mechanic	50
Polymer Assistant Operator	120 - 385
Class 1 Operator	120 - 385
Class 2 Operator	120 - 385
Alternate	120 - 385
Spare	120 - 385
Dryer Operator	95 - 350
Monomer Still Operator	50 - 85
Flash Dryer Operator	15 - 100
Tankcar Unloader	100
Monomer Transfer Operator	100

*Excursions up to 4000 ppm were measured in the Wet End Operations.

Table 2. Summary of Vinyl Chloride Measurements, By Job Classification, in Production Unit II., 1953-1959.

Job Classification	TWA 8-Hour ppm By Volume
Foreman	5 - 10
Utility	10
Janitor	10
Handyman	10
Alternate	50 - 65
Blender-Packer	10 - 25
Tank and Wheel Operator	125 - 140
Dryer Operator	50 - 60
Polymerizer Operator*	50 - 65
Clerk	.5
Mechanic	50
Coagulator**	135 - 825

*Excursions up to 600 ppm were measured.

**Excursions up to 1300 ppm were measured.

Table 3. Summary of Vinyl Chloride Measurements, By Job Classification, in Production Unit 1, 1960-1963.

Job Classification	TWA 8-Hour ppm By Volume
Dry End Operations	
Foreman	5
Shipping Clerk	5
Utility	5
Packer	5
Assistant Operator	5
Shift Miller	5
Wet End Operations	
Foreman	10
Crew Leader	10
Mechanic	25
Polymer Assistant Operator*	25 - 80
Class 1 Operator*	25 - 80
Class 2 Operator*	25 - 80
Dryer Operator	25 - 85
Monomer Still Operator	25 - 45
Flash Dryer Operator	10 - 15
Tankcar Unloader	25
Monomer Transfer Operator	25

*Excursions up to 500 ppm were measured.

Table 4. Summary of Vinyl Chloride Measurements, By Job Classification, in Production Unit II, 1960-1966.

Job Classification	TWA 8-Hour ppm By Volume
Foreman	5
Utility	10
Janitor	5 - 15
Handyman	5 - 15
Spare	30 - 40
Alternate	20 - 50
Blender-Packer	10 - 20
Tank and Wheel Operator*	140 - 240
Dryer Operator	20 - 100
Polymerizer Operator	20 - 50
Clerk	5
Mechanic	50
Coagulator	30 - 240

*For excursion levels see (19), Baretta, E. D., et al.

Table 6. Observed And Expected Deaths, By Cause, Including And Excluding Those Employees Exposed To Arsenic, 1942-1973.

	Total Population		Total Population Less Arsenic Exposed	
	Obs.	Exp.	Obs.	Exp.
All Causes	89	100.1	79	89.1
Total Malignancies	20	17.9	13	16.0
Cancer of the Respiratory System	7	5.8	4	5.2
Cancer of the Digestive System and Peritoneum	7	5.3	5	4.7
Malignant Neoplasm of Stomach	1	NC*	1	NC
Malignant Neoplasm of Liver and Intrahepatic Bile Ducts	0	NC	0	NC
Malignant Neoplasm of Intestines or Rectum	5	NC	3	NC
All Other Digestive and Peritoneum Ca.	1	NC	1	NC
All Other Sites	6	6.8	4	6.1
Diseases of the Cardiovascular System	41	49.5	40	44.4
External Injuries	12	13.0	11	11.4
Cirrhosis of Liver	3	3.1	3	2.7
All Other	12	16.4	11	14.6
(Death Certificates Not Available)	1	--	1	--

* Not Compiled

Table 7. Case Summaries of Seven Subjects Who Were Exposed To Arsenic As Well As Vinyl Chloride And Whose Death Was Due To Cancer.

Case Number	Date Of First Vinyl Chloride Chlorinated Monomers Exposure And Exposure Duration	Year Of Death	Age At Death	Primary Site Of Malignancy	Autopsy	Family Cancer History	Smoking History	Other Significant Exposure
1	1947 86 months undetermined exposure	1959	60	Prostate	---	Unknown	Pipe	Arsenic
2	1949 3 months low exposure	1959	60	Lung	No	No	3/4 Pk/Day	Arsenic
3	1949 111 months low exposure	1964	68	Lung	Yes	No	1 Pk/Day	Arsenic
4	1952 3 months low exposure	1971	41	Brain	No	No	1-1/4 Pk/Day	Arsenic
5	1941 220 months High exposure 272 months total exposure	1973	63	Lung	No	Brother (1)	Unknown	Arsenic
6	1951 177 months undetermined exposure	1966	49	Colon	---	Unknown	Unknown	Arsenic
7	1942 4 months high exposure	1971	66	Colon	---	Unknown	Unknown	Arsenic

Table 8. Duration of Exposure By Level of Exposure For Each Exposure Grouping (Arsenic Workers Excluded)

Exposure Group And Level of Exposure	Number of Employees With Cumulative Exposure of:			
	< 1 Year	1-9 Years	10-19 Years	20+ Years
High Exposure Group				
Low to High Levels	33	64	39	27
High Levels Only	73	71	19	0
Intermediate Exposure Group				
Low to Intermediate Levels	29	38	6	0
Intermediate Levels Only	32	36	5	0
Low Exposure Group				
Low Levels Only	127	50	3	1
Unmeasured Exposure Group				
Unmeasured or Low Levels	39	44	16	6

Table 9. Observed And Expected Deaths By Exposure Intensity And Duration of Exposure, 1942-1973. (Arsenic Workers Excluded)

Exposure Intensity and Duration	Deaths Due To All Causes		Deaths Due To Malignant Neoplasms	
	Observed	Expected	Observed	Expected
High Exposure				
Total	27	28.2	9	5.1
< 1 Year	14	12.8	3	2.2
1+ Year	13	15.4	6	2.9
Intermediate Exposure				
Total	11	16.5	2	2.9
< 1 Year	5	7.9	-	1.4
1+ Year	6	8.6	2	1.5
Low Exposure				
Total	23*	23.4	1	4.1
< 1 Year	16	13.7	-	2.4
1+ Year	7	9.7	1	1.7
Unmeasured Exposure				
Total	18	21.0	1	3.9
< 1 Year	6	8.5	1	1.5
1+ Year	12	12.5	0	2.4

* Cause of death was not available for one decedent in the low exposure group with less than one year exposure.

Table 10. Observed And Expected Deaths 15 Years After Initial Exposure By Exposure Intensity And Duration of Exposure. (Arsenic Workers Excluded)

Exposure Intensity And Duration	Deaths Due To All Causes		Deaths Due To Malignant Neoplasms	
	Observed	Expected	Observed	Expected
High Exposure				
Total	20	16.4	8	3.2
<1 Year	9	6.6	3	1.3
1+ Years	11	9.8	5	1.9
Intermediate Exposure				
Total	4	7.8	0	1.4
<1 Year	2	3.7	0	.7
1+ Years	2	4.1	0	.7
Low Exposure				
Total	9*	12.1	1	2.4
<1 Year	7	6.6	0	1.3
1+ Years	2	5.5	1	1.1
Unmeasured Exposure				
Total	11	10.8	0	2.2
<1 Year	3	4.2	0	.8
1+ Years	8	6.6	0	1.4

* Cause of death was not available for one decedent in low exposure group with less than one year of exposure.

Table III. Case Summaries of 15 Subjects Who Were Exposed to Arsenic and Who Died From Cancer.

Case Number	Date of First Vinyl Chloride Exposure and Exposure Duration	Year of Death	Age At Death	Primary Site of Malignancy	Autopsy	Family Cancer History	Smoking History	Other Significant Exposure
	High Exposure Group							
8	1950 19 Months High Exposure 168 Months Total Exposure	1964	54	Stomach	Yes	Mother	Unknown	---
9	1949 41 Months High Exposure 209 Months Total Exposure	1966	53	Lung	Yes	Mother	1 Pk/Day - 30 Yrs.	---
10	1951 4 Months High Exposure 120 Months Total Exposure	1968	69	Lung	Yes	No	Unknown	---
11	1943 203 Months High Exposure 287 Months Total Exposure	1969	56	Rectum	No	Mother Bro (2) Sis (1)	Unknown	---
12	1941 222 Months High Exposure 317 Months Total Exposure	1969	61	Squamous Cell Site (?)	Yes	No	1 Pk/Day - 20 Yrs.	---
13	1950 65 Months High Exposure 119 Months Total Exposure	1971	45	Leukemia	No	No	No	Benzene
14	1945 154 Months High Exposure 300 Months Total Exposure	1972	54	Lung (?)	No	No	2 Pk/Day - 36 Yrs.	---
15	1950 5 Months High Exposure 191 Months Total Exposure	1972	62	Lung	No	No	1/2 Pk/Day - 30 Yrs.	---
16	1948 8 Months High Exposure 64 Months Total Exposure	1973	62	Colon	No	No	1 Pk/Day - 45 Yrs.	---
	Intermediate Exposure Group							
17	1954 25 Mos. Intermed. Exp. 51 Mos. Total Exposure	1958	61	Brain	?	No	Unknown	---
18	1945 30 Mos. Intermed. Exp. 84 Mos. Total Exposure	1960	71	Pancreas	No	Unknown	Unknown	---
	Low Exposure Group							
19	1952 66 Months Low Exposure	1970	51	Lung	Yes	Unknown	Unknown	---
	Undetermined Exposure Group							
20	1952 5 Mos. Undeterm. Exp. 14 Months Low Exposure	1954	60	Cecum	Yes	Father	Unknown	Benzene

Table 12. Case Summaries of Two Deaths For Which Malignant Neoplasms Were Secondary To The Underlying Cause of Death.

	Subject 21	Subject 22
Cause of Death From Death Certificate	Acute Pulmonary Edema (Immediate) Myocardial Infarction (hours) Other significant conditions Bronchiogenic Carcinoma right lung.	Massive Old Myocardial Infarction (7 days) Sigmoid Carcinoma With A-R Resection (8 months).
Date of first vinyl chloride exposure and exposure duration	1950 3 months low exposure.	1950 1 month low exposure.
Year of Death	1968	1972
Age at Death	50	50
Autopsy	Yes	Yes
Family Cancer History	No	No
Smoking History	1 package/day	1 package/day
Other Significant Exposure	--	--

Statement of:

Dr. Richard W. McBurney

Corporate Medical Director
Diamond Shamrock Corporation

Prepared for presentation at:

Department of Labor Hearings on Vinyl Chloride;

Occupational Exposure Standard

June 25, 1974

I am Dr. Richard W. McBurney, Corporate Medical Director of Diamond Shamrock Corporation. I am a physician and have held my present position full-time with Diamond since 1971. Prior to that time I was retained by Diamond Shamrock as a consultant for a ten year period.

I am a Diplomate of the American Board of Surgery and have held teaching positions at Western Reserve University Medical School in the past. I am a member of numerous professional societies and associations.

I have reviewed the medical evidence available to date concerning the possible adverse effects on employees from exposure to vinyl chloride vapors, including the reports of experimental and other test data recited in the preamble to the proposed regulations as published in the Federal Register. I and my staff have also conducted a comprehensive review of the medical condition of the present and past employees of Diamond Shamrock whose work assignments involve exposure to vinyl chloride. Based upon my review of all of this data, I am of the opinion that the proposed requirement that the vinyl chloride exposure for workers be reduced to a "no detectable" level may be unnecessarily restrictive and not yet supported by available medical evidence.

The experimental data reported in the Federal Register as justification for the proposed standard establish beyond question that vinyl chloride is a carcinogen in the animals tested. Further, the data reveal a very definite dose-response pattern with sharply reduced carcinogenic effects as exposure levels are reduced. In my judgment, it is also proper to conclude that vinyl chloride should be treated as a carcinogen for man. This follows from the histological similarity of the angiosarcoma tumors found in vinyl chloride workers to those induced in test animals.

But there is no basis in the available data for determining the dose-response pattern for man. I believe there is general agreement in the scientific community that the dose-response level found to exist in test animals cannot automatically be extrapolated to determine the dose-response level for man. Based on the available data from which conclusions may be drawn, and I refer to the mortality study by Tabershaw, the medical facts presented earlier in these hearings by Dr. Dernehl, my own investigation of the medical condition of our workers and the high levels of exposure in the past, I would believe the dose-response effect for man to be higher than that in rodents.

I would like at this time to present a summary of the results of our medical examinations. We have recently completed a comprehensive physical examination of all Diamond Shamrock workers presently engaged in plastics manufacture and all active employees who had spent one year or more in the plastics area. This involved the examination of 709 persons by a number of physicians. All of the medical personnel had been informed of the medical nature of VCM related disorders, including specifically angiosarcoma of the liver. Special attention was given to the skin, hands, lung fields and abdominal organs. SMA-12 blood tests were conducted on all persons examined, as well as chest and hand radiographs. At this time I am able to report that all of the employees examined are in good health and we found no medical evidence that any employee is suffering from angiosarcoma of the liver.

In the course of these examinations, special attention was given to the "liver fraction" of the SMA-12 blood reports. The results were comparable to what we have found in our office workers or workers in other facilities with no exposure to VCM. Specifically, of the 709 persons tested, only 47 disclosed liver elevations and, in those cases, as I have said, there was no medical evidence to associate those elevations with angiosarcoma. The chest radiographs revealed no significant abnormalities not found in other employees not exposed to

VCM. The hand radiographs confirmed one previously diagnosed case of acroosteolysis, and disclosed two other cases not previously recognized.

In addition to the examination of the 709 current employees, we conducted a follow-up survey of all 190 former employees who may have been exposed to VCM for a period of one year or more. We were able to locate or obtain information about all but one of these former employees. Of this group, 179 are retired or actively engaged in other employment and all are thought to be in a good state of health. Ten deaths have occurred in this group and the death certificates were examined. In no case did the survey reveal any angiosarcoma. Of the deaths that occurred there were the following: one suicide, one accident, one carcinoma of the esophagus, one carcinoma of the large intestine, and six due to degenerative diseases of the heart or blood vessels.

The results of our medical examinations and survey are particularly significant in light of the relatively high VCM levels to which workers were exposed in the past. During the early years of PVC production, 1953-1964, attention was given to VCM vapors only because of the anesthetic qualities and the explosion hazard. Since the explosion hazard occurs at upward of 30,000 ppm and the anesthetic effects at 1000-5000 ppm, the VCM levels in work areas were undoubtedly quite high.

Many of our older workers have experienced the intoxication due to VCM vapors and anesthesia has occurred in some cases. Accordingly, it would appear that excursions to thousands of parts per million have occurred in the past.

In the last decade, 1964-1973, VCM levels of 250 to 1000 ppm, and perhaps even higher, were commonplace because odors of VCM were frequently evident. The greatest frequency of these higher levels occurred in connection with reactor cleaning operations, with other high levels in the monomer unloading areas and latex screening areas.

During the months of June through October, 1973, efforts were conducted by the instrument group of Diamond's Research Department to obtain time-weighted averages for both of our facilities. The TWA values were quite variable, but on the average were 160 ppm.

Thus, it is clear that over the past twenty years our workers have been exposed to VCM levels substantially in excess of the current emergency standard of 50 ppm, and, of course, much greater than the proposed "no detectable" limit. Since establishment of the emergency standard of 50 ppm, we have obtained limited data dealing with the TWA levels of workers in our plants. These have averaged 5 ppm for one facility and 25 ppm for the other.

We recognize that more data will be needed and more studies will have to be conducted before a final scientific opinion can be rendered on the carcinogenic effects of VCM in man and the exposure levels which will produce those effects. The results of the NIOSH epidemiological studies currently underway will be of great interest and value, but those studies do not cover the entire industry. The VCM and PVC producers could make a useful contribution by conducting similar studies on present and past workers in their own plants in order to provide as complete a picture as possible of the medical condition of workers who have been exposed to VCM.

While this additional data is being gathered and analyzed, Diamond Shamrock is exerting every effort to reduce employee exposure to VCM to the lowest possible levels. At this time we are complying with the OSHA emergency standard of 50 ppm by the use of modified work practices, engineering changes and fresh air masks. Process redevelopment is underway and materials are on order to further implement reductions of VCM vapors. We endorse the gradual reductions in VCM levels as proposed by SPI. In addition, as a prudent corporation, we are hopeful that we will be able to reach those levels in a shorter period of time, and we intend to do all that we can to attain even lower levels of exposure.

Taking into account the clear dose-response effect of VCM in the rodent population, the present good health of our workmen, the paucity of cases of angiosarcoma in the highly exposed workmen in older facilities, the facts presented in the Tabershaw mortality report and in Dr. Dernehl's testimony earlier in this hearing, and, finally, the tremendous reduction in exposure levels Diamond Shamrock has already achieved and plans to achieve in the future, I am of the opinion that our workers are now at low risk insofar as VCM hazard is concerned.

Before concluding, I want to add a word about the medical surveillance provisions of the proposed standard. We concur with the Department of Labor's stand that there is a need for long-term medical surveillance. However, we disagree with the extent to which the proposed standard invades the province of the physician by spelling out in minute detail the type and timing of tests and other procedures that must be employed. Given the wide publicity and attention the vinyl chloride problem has received, there is no reason to suggest that physicians charged with the responsibility of monitoring the health of workers exposed to vinyl chloride will not take all proper steps, including tests of liver functions, to insure early detection and proper diagnosis and treatment of any vinyl chloride related problems.

On this point, OSHA would do well, in my judgment, to follow here the precedent that was set in the medical surveillance requirements established in the carcinogen standard for bis-chloromethyl ether (39 Fed. Reg. 3776), a material more toxic than vinyl chloride by several hundred fold. The medical surveillance provisions for that carcinogen are limited to three short paragraphs which rely chiefly on the sound, professional judgment of the examining physician. There is no need to go beyond that here.

of their raw material supply. Less than 3 percent of our PVC production is exported. Our customers for PVC include companies which manufacture plastic pipe, electrical wire and cable, packaging film and sheet, resilient floor covering, coated fabrics, and a host of specialized extruded and molded parts which find their way into almost every facet of American industry and life, but particularly automotive, household furnishings, appliances, and so forth.

Our interest in the vinyl chloride problem extends beyond our production of PVC. We are also one of the principal U. S. producers of chlorine, and a significant percentage of Diamond's chlorine is converted into VCM and ultimately into PVC.

At the other end of the spectrum, Diamond has a subsidiary in New York City, Harte and Company, which uses PVC to produce vinyl film and sheeting and vinyl molded products.

Diamond is vitally interested in the proposed OSHA standards for occupational exposure to vinyl chloride for two reasons:

First, we are concerned about the health and welfare of the workers in our plants, and we want to do all that we can to insure that our employees are not subjected to any undue hazards in connection with their employment.

Second, we want to insure that the final regulations not go beyond what is necessary to protect the health of our

employees. An overly restricted standard could well spell disaster for our PVC operations.

In fact, if the proposed standard is placed into effect in its present form, our entire PVC operations would almost certainly have to be shut down.

Our position in these hearings may be briefly summarized as follows:

First, we believe the proposed requirement that vinyl chloride exposure in work areas be reduced to a "no detectable" level is overly restrictive and has not been justified by the evidence available to date.

Dr. Richard W. McBurney, Corporate Medical Director of Diamond Shamrock, who is with me today, will review the medical data on which the proposed standard is based, and explain why we believe the "no detectable" level is not necessary to insure the health of our workers.

In our judgment, the cases of worker illness recently discovered in industry plants are the delayed result of conditions that were common formerly, but are no longer present in today's plants.

Second, we are convinced the standard as now proposed cannot be complied with by our plants. Mr. George D. Williams, Production Manager of our PVC plant at Deer Park, Texas, will explain why the proposed "no detectable" level is not feasible in the present state of the art, or in the foreseeable future.

Mr. Williams will report that we are presently able to achieve the 50 part-per-million emergency standard set by OSHA, and that we believe we will be able to implement further reductions in time. Specifically, we believe we will be able to comply with the exposure levels recommended earlier in these hearings by SPI, and we endorse those SPI proposals, with one exception, which I will mention shortly.

Finally, we believe the test data reported earlier by Mr. Rodney Becker of our company, that was during the course of the SPI presentation, demonstrate clearly that fabricators and compounders who use PVC resins containing less than 1/10th percent or 1,000 parts per million of vinyl chloride monomer can safely be exempt from coverage in the final regulation.

Dr. Howard Everson, who is Director of Safety and Environmental Engineering for Diamond Shamrock, will explain why we believe the SPI proposal that the exemption level be reduced in 1977 to 1/100th of one percent or 100 parts per million is unnecessary.

Diamond has produced PVC since 1953. We pride ourselves on being an efficient producer and one of the technological leaders in the industry. We employ a large number of engineers, chemists, and other technical personnel to insure that our operations are safe for our employees, and meet both customer requirements and government regulations.

In the last year alone, we have appropriated close to

all proper steps, including tests of liver functions, to ins early detection and proper diagnosis and treatment of any vinyl chloride related problems.

On this point, OSHA would do well, in my judgment, to follow here the precedent that was set in the medical surveillance requirements established in the carcinogen standard for bis-chloromethyl ether (39 Fed. Reg. 3776), a material more toxic than vinyl chloride by several hundred fold. The medical surveillance provisions for that carcinogen are limited to three short paragraphs which rely chiefly on the sound, professional judgment of the examining physician. There is no need to go beyond that here.

JUDGE MYATT: All right.

Mr. Kline?

MR. KLINE: Dr. Lassiter has some questions.

DR. LASSITER: Dr. McBurney, on your testimony on page two, you express the opinion, or judgment, that it was proper to conclude that vinyl chloride should be treated as a carcinogenic for man.

Do you base this on the animal data, the human data, or both?

DR. McBURNEY: I think it would be both.

Generally, on the human data.

DR. LASSITER: Okay, so you concluded it should

Do you feel it is indeed a carcinogenic in man?

You say it is treated as one.

Do you feel it is carcinogenic generally to humans?

DR. McBURNEY: Yes.

DR. LASSITER: You also mention at the bottom of the page you believe that the dose-response effect for man be higher than in rodents.

What specific data do you base this conclusion on?

DR. McBURNEY. It is the general data.

I think there is a pattern evolving, and has been for a week, and it is one that every one suspected, that in the past there have been marked, higher levels, and in the northern plants where the higher levels were even more manifest because of indoor facilities, there was a much more marked effect in the carcinogenic and other factors.

In the southern plants, in the plants that are open air, where even though there weren't the proper hygienic precautions, just the outdoor effect had the affect of reducing the values.

I think we are seeing this throughout the industry. I think an industry survey will show this.

There is no proper sampling that you can turn to and put your finger on and sa lock, we have 1,000 or 10,000, it just isn't there.

ws-20

DR. LASSITER: The comparison you make here between man and rodent, which you say you believe the exposure, or the dose-response is higher in man than in rodent, what do you make this comparison on?

DR. McBURNEY: Just the viability.

DR. LASSITER: You need some.

DR. McBURNEY: Yes, on the Maltoni data.

DR. LASSITER: So you feel, based on the Maltoni data, that the dose-response in man, this is based on the Dow experience, based on these two studies, this general group of studies that the dose-response in man is higher than that in rodents, is this correct?

DR. McBURNEY: This is correct.

DR. LASSITER: Were you here to hear Dr. Snyder when he testified that he felt just the opposite?

DR. McBURNEY: Yes, I heard Dr. Snyder.

DR. LASSITER: What would be your difference with his conclusions, then?

DR. McBURNEY: Well, I am not sure.

Dr. Snyder I thought was a theoretical mathematician, a bio-statistician, and I just don't reach the same conclusion that he does on a practical basis.

DR. LASSITER: Well, he was talking biologically when he mentioned that the rodent, of course, having a more rapid metabolism, et cetera, would perhaps handle a metabolite

faster than that in man, and perhaps use this type of analogy to show that the rat would be less susceptible than man.

DR. McBURNEY: Yes, I know he did, and he also drew the conclusion that most days when it was asked, he didn't specify, but he said a lot of agents are much more toxic for man than rat, but he didn't put it on a weight for weight basis.

If a milligram will kill a rat, does it take a half milligram to kill a man?

This was the defect I think in his testimony, and I would have to go and reread it, but I just can't believe -- well, even though you toook the rodent and interpolated it to man, you are closely approaching a low risk area, and at the levels of exposure that we are following, a fifth, one part in 25, this is time weighted average.

These are markedly less than our people must have been exposed to and were exposed to a number of years ago.

DR. LASSITER: If your conclusion here would be wrong, that is that man would be, the dose response effect for man would be lower than that for rodents, would it be more prudent to err on the side of man in making judgments concerning these standards when we have animal standards?

DR. McBURNEY: Yes, your statement is absolutely correct.

DR. LASSITER: You mention your survey and your

conclusion, and I think we have seen that several industries involved in several of their own studies to supplement what is going on with the MCA sponsored studies, and also the NIOSH activities, with the examination, I think, of about 700 people, do you have anything to say -- I don't mean to pin you down to exact, but to years of exposures?

DR. McBURNEY: Yes, I have that broken down, 20 to 25 years, are 17; 15 to 20 years are 18; ten to 15 years are 33, and the remainder are less than ten years.

DR. LASSITER: Is this in the report or supplemental report?

DR. McBURNEY: I just put it together.

DR. LASSITER: Would you submit this also?

Thank you.

On page seven of your testimony you say you were of the opinion that your workers now are at a low risk insofar as vinyl chloride hazard is concerned.

We have addressed this question of risk several times during the hearings.

What do you consider to be the low risk that your employees are exposed to?

DR. McBURNEY: A specific number?

DR. LASSITER: Well, what do you mean by terms of low risk?

Can you define it any further?

have no real objection to specifying them. We will do it.

DR. LASSITER: Okay, I was going to ask you if you have some others you might add.

DR. McBURNEY: Not at this time.

DR. LASSITER: Then to go along with this, let me ask you if you think that all the employees that would be a possible risk would have access to a physician as a board certified in occupational medicine and as astute as the physicians you have listed here that would be charged with this responsibility, do they all have access to this type of position?

DR. McBURNEY: I don't know whether they do or not, but I think it would be prudent for the management to get such physicians.

DR. LASSITER: Thank you.

MR. KLINE: Doctor, this question may have been asked, or very close to this question may have been asked, and if you consider it the same question, you don't have to answer it, but leaving aside the question of technical and economical feasibility, what level of exposure would you say with respect to vinyl chloride, exposure of employees?

DR. McBURNEY: Mr. Kline, I think I will duck that question, because I would rather not be on the record as having to recommend anything.

I think this, and this is the whole thrust of what I said I thought, and perhaps I didn't couch it as

succinctly as I should have, but we have had plants operating since 1953 that, having talked with the management, and having talked with the workmen, and having seen what went on, that we have obviously very, very high levels, and by high, I mean thousands of parts per million.

Now, we have, as nearly as we can, we have treid to establish the health of that workman as of this period of time.

I don't find anything markedly different.

I have not had enough time to do much with this work in the hectic day.

Now, if I can look at these workmen, and I don't know, someone is going to ask this question, I don't know, they haven't been developing carcinogen now.

All I know at the presne time they are fairly healthy, and they have had little effect, and if we are to reduce this by several hundred fold to this poing of 25, 40, 50, and what is the difference between ten, 15 and 20. It is a matter of semantics.

I do not believe that that will be a great deal of harm. This is why there is the low risk, and it is my common sense that says this more than anything else.

MR. KLINE: Would the level be below 50 parts per million?

DR. McDUFFEY: Well, I can't answer that.

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environmental area.

Dr. Everett will amplify this.

MS. HRICKO: So my questions about the relay of information to these physicians would best go to him later?

DR. McBURNEY: Yes.

MS. HRICKO: Thank you, sir.

JUDGE MYATT: Are there any other questions?

MR. CONNELLY: Doctor, for all practical purposes, is there any difference between 15 ppm in terms of medical significance on an employee, and say 25 parts per million, PCM?

DR. McBURNEY: Is a personal opinion. I do not think there is.

MR. CONNELLY: Thank you.

JUDGE MYATT: Any other questions?

Doctor, have a good trip.

Rogers/ms
f.s. Norris

MR. CONNORS: I would like next to introduce George Williams, Production Manager of our Deer Park, Texas, PVC plant.

STATEMENT OF GEORGE D. WILLIAMS, PRODUCTION MANAGER, DIAMOND SHAMROCK CHEMICAL COMPANY

MR. WILLIAMS: My name is George D. Williams. I have been employed by Diamond Shamrock Chemical Company for 13 years, 11 of which have been as Engineer, Engineering Manager, and now Production Manager in the PVC facility at our Deer Park, Texas, complex, which has produced PVC since 1953.

Under my supervision are approximately 100 personnel.

I will comment on the feasibility of the proposed engineering controls and work practices, based upon my experience with PVC production. In particular, I will discuss the following topics:

1. Proposed undetectable level of vinyl chloride.
2. Respiratory protection, Section (g).
3. Hygiene facilities and practices, Section (i).
4. Regulated areas, Section (d).
5. Protective clothing, Section (h).
6. Maintenance and Decontamination, Section (l).

1. Proposed Undetectable Link.

Although we have been able to greatly reduce ambient VCM levels in our plants, an undetectable level of VCM is not feasible in the emulsion and suspension processes used by

ms-2

Diamond. Production of PVC by these methods involves many stages and operations.

First is the reaction section containing numerous pressure vessels. This is a batch operation with vessels being continuously filled, discharged, and opened for cleaning.

Downstream from the reaction section is the slurry processing section where most, but not all, unreacted VCM is removed and recovered for reuse, and the PVC powder is separated from the carrier liquid, usually water.

The PVC powder is then dried in rotary, fluid bed, flash, or spray dryers, and is then stored in silos for final packaging; or is processed through compounding mixers, mills and extruders before packaging. Each of these operations releases a small but measurable amount of VCM.

In June of 1973, we began an intensive effort to locate sources of emissions of VCM in our plants, and instituted an ongoing program of reduction or, where possible, elimination of those emissions.

In March of this year, our company formed three engineering teams to determine the feasibility and means of reducing VCM in plant air to an undetectable level -- less than 1 ppm.

This task force identified over 500 potential sources of vinyl chloride exposure in our facilities. In their opinion, VCM emissions from these sources could be reduced considerably but not to anywhere near an undetectable level.

ms-3

The limitations of the mechanical integrity of the vast numbers of vessels, agitator and pump seals, and thousands of gaskets, flanges, and valves make it impossible to eliminate or contain all VCM emissions.

We believe, however, that it is feasible to reduce the average employee exposure to vinyl chloride well below the Emergency Temporary Standard of 50 ppm. We at Diamond Shamrock have already succeeded in bettering that standard, and we can go even lower, given sufficient time for engineering, procurement and construction.

We believe the SPI proposed limits are feasible and realistic:

(a) 40 ppm ceiling and 25 ppm TWA by October 5, 1974.

(b) 25 ppm ceiling by October 5, 1975.

(c) 25 ppm ceiling and 10 ppm TWA by October 5, 1976.

To attain exposure levels lower than those I have just described may well be possible, but if it can be done, it will certainly require new technology and construction which will take several years to complete.

2. Section (g), Respirators.

The use of respirators is not a solution to the VCM problem. Based on my experience, use of respirators is suitable only for short duration situations where significant VCM concentrations have been detected.

I have indicated earlier that there is no way we can

possibly reduce our emissions to a "no detectable" level.

Therefore, if the final standard includes that requirement, we will be faced with only two alternatives -- cease operations or require all operating personnel to wear respirators at all times.

What must be emphasized here is that our technical inability to preclude even very slight emissions is not limited to just a few isolated operations.

From start to finish, the process necessarily includes transfer points, valves, and other elements which cannot be made airtight. Consequently, to continue our operations under a "no detectable" requirement would mean that our entire work force would be in respirators at all times. This may create a greater safety problem than it would solve, for the following reasons:

A. Operating a PVC unit is a physically demanding job requiring considerable mobility, and the awkward breathing equipment can cause increased accident. Manways in the pressure vessels are quite small, and the proposed safety gear impedes entry into the vessels and prevents rapid exit from the vessels if an emergency should develop.

B. Masks restrict vision, also leading to increased injuries.

C. An employee hazard may be created if the air supply becomes depleted or contaminated.

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D. The discomfort of face masks over an extended prior creates fatigue and distraction, which can itself result in accidents.

E. Verbal communications to fellow employees would be hindered, thereby resulting in increased accidents.

Even at the more realistic exposure level suggested by SPI, the proposed Federal requirements on respiratory protection in subsection 1910.93q(g) still need certain modifications.

They should be amended to recognize the need for varying equipment to meet varying needs. Therefore, mandatory full face pieces, mandatory bulky and short-duration, self-contained breathing apparatus should not be specified.

Appropriate provisions for canisters and for fresh air continuous flow systems as choices should be allowed, depending on the nature of the hazard.

3. Section (i), Hygiene Facilities and Practices.

We agree that food, beverages and cigarettes should not be consumed where there are ambient VCM concentrations, but we now have pressurized buildings and rooms with conditioned and remote air supplied where there is no risk of exposure to VCM.

We proposed that the regulations recognize that safe locations within a production facility can exist and are acceptable.

4. Regulated Areas.

As proposed, regulated areas are established without regard to the VCM level existing in the facility. This unnecessarily restrictive definition should be changed to include only those areas where the VCM level has been found to exceed the standards. These areas are readily identifiable and access to them can be easily controlled.

The proposed regulation also prohibits non-employees from entering the regulated area. This is not feasible, as there are non-employee personnel essential to our operations. They include truck drivers for raw material and finished goods, service personnel, vendors, and engineering and construction contractors.

5. Section (h), Protective Clothing.

The proposed regulation raises the question of whether the full-bodied protective clothing required within the regulated area must be completely impervious to vinyl vapors.

If so, it would also be impervious to the air circulation necessary for body cooling.

My personnel cannot work eight hours in Texas heat and humidity if so dressed.

For routine duties in the regulated area, porous, cotton-like clothing should be adequate, and the clothing definition should be modified.

The mandatory showers and the requirement for a

MR. KLINE: Thank you very much for your efficiency, sir, thank you.

MR. EVERSON: What is left?

MR. KLINE: Pardon me?

MR. EVERSON: What is left?

MR. KLINE: Did you bring anything else with you?

MR. EVERSON: No, I mean of your list. I want to make sure that we don't miss anything.

MR. KLINE: I think that is it.

JUDGE MYATT: All right, we are going to at this point add as 25E, the latest exhibit from Diamond Shamrock, it is entitled VCM -- what is it entitled?

MR. WILLIAMS: I am sorry it doesn't have a cover. It is VCM-VAC vinyl acetate trichlor.

JUDGE MYATT: Did you get that, Mr. Reporter?

THE REPORTER: VCM what?

MR. WILLIAMS: VCM vinyl acetate trichlor.

JUDGE MYATT: All right, that will be in the record as 25E.

(Document above referred to was marked as exhibit 25E)

MR. KLINE: I haven't seen those data but perhaps you could just tell me briefly, does the Texas plant have a lower general level than the Delaware plant?

MR. WILLIAMS: Perhaps to save many questions,

just review briefly that data I gave you --

MR. KLINE: If you could, we would appreciate it, very briefly.

MR. WILLIAMS: The first time weighted average data, Deer Park plant, 66 samples taken during March of 1974, and averaged 5 parts per million. These ranged from less than one part per million to a high value of 26 parts per million.

53 of these 66 samples were less than ten parts per million.

Our Delaware City plant of 41 samples during March and April of this year averaged 25 parts per million in a range of two as a low and 138 parts per million as a high.

Only 13 of these were less than ten parts per million. As to ceiling data, this is ten minute data. ceiling data.

218 samples at Deer Park, for April, May and June. I did not average all those but I think it is between 10 and 12 parts per million average.

At Delaware City there were 170 samples, back on the other data of the Deer Park samples.

Owing to give a breakdown, distribution of where these 218 samples were, there were eight over 40, there were 11 over 25, there were 34 above ten parts per million and as I recall, 80 per cent of them were one part per million or

greater.

The high value of these 218 was 2,375 parts per million.

The Delaware City results, 170 samples, again not having -- there doesn't seem to be any calculators in the attorney's office, I would just look at it and would guess it was 40 parts per million.

The breakdown on that, there were 35 samples above 40 parts per million and 54 samples over 25 parts per million and 102 samples were over 10 parts per million.

The high value at Delaware City as sampled was 1,389.

MR. KLINE: Could you give us the approximate ages of these plants?

MR. WILLIAMS: The plant in Deer Park was built in 1953 so it is 21 years old and the plant in Delaware City was built in 1966, eight years old.

MR. KLINE: Mr. Connors, on page 3 of your testimony you indicated that no detectable level had not been justified by the evidence available to date.

In your view, what would justify that type of level that is no detectable?

MR. CONNORS: Evidence that it was both feasible and necessary. In order to protect the health of the workers.

MR. KLINE: Let us talk for a moment about the

recommendation that you had to the extent that it coincides with SPI's.

I will get to the difference in a moment.

Upon what basis do you conclude that the level should be 25 of time weighted average in the PBC plants with excludance to 40?

MR. WILLIAMS: This is primarily on the basis of when we feel our Delaware City plant can become in compliance with those numbers.

MR. KLINE: Upon what basis did you conclude that it would take that amount of time for your Delaware plant to reach that level?

MR. WILLIAMS: We have considerable number of programs underway at this time and based on the projected completed date of current projects, that it is just about when we would come out.

I think the date that we feel that we could be in that range is slightly earlier than Delaware, January of '76 instead of October.

But there is one big project which we are just now engineering at Delaware in the course of ventilation that could make it very difficult to complete for October of '76.

MR. KLINE: Would it be fair to state that it just represents your best judgment?

MR. WILLIAMS: It is my engineering judgment, yes.

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MR. KUHN: Let us talk about .1 per cent and .01 per cent for the resins.

First question is, have you been able to establish a relationship between the percentage of unreacted monomers and the exposure in the ambient air?

MR. EVERDELL: In Dr. Zocher's data, it was interesting to me and I think you have it in the record, he has samples that are anywhere from -- down to a few tenths of parts, to sum up, and several hundred parts and there is one set it up at 650 parts and we have one isolated sample.

I don't hold much to that except it is good to have and see what happens at higher levels and that one had 1600 parts in it and there is a large variation.

As a matter of fact, in many instances, even at 650 the levels were down at the one part per level. I think the data shows that.

MR. KUHN: Incidently, why is the Delaware plant have greater exposure than the Texas plant?

MR. EVERDELL: Do you want to answer that?

DR. WILLIAMS: Of course it is an enclosed plant where the Deer Park plant is open.

This was mentioned by Dow and Texas, there is 15 or 20 mile an hour breeze going through there and at Delaware you don't have that breeze.

DR. COMMONS: Could I make one comment, sir?

There is a difference in product mix also affects the two plants. Some products will provide higher levels.

MR. KLINE: Could you go into that a little bit and tell us which product it is that have higher exposure level?

MR. CONNORS: Well, there are different types, I am not prepared to go into too much in detail on it, but we do have particularly one product at Delaware City where we invariably get higher worker exposures in several areas of the plant, simply because the resin is not depleted of unreacted vinyl chloride monomer.

MR. KLINE: Which resin, sir?

MR. CONNORS: Is it necessary that we discuss that or that I answer that?

MR. KLINE: Well, I think --

MR. CONNORS: To some extent it might be proprietory information.

MR. KLINE: Well, I guess --

MR. CONNORS: I can tell you the general type. It is a suspension produced resin which has special uses in plastosols.

MR. KLINE: Now just talking about major engineering controls and work practices now --

MR. WILLIAMS: I am sorry, I wasn't listening.

MR. KLINE: You are probably not the only one. Are there any major engineering control differences

between the two plants?

MR. WILLIAMS: No, we might be at slightly different places in our engineering controls but we are both on the same programs.

MR. KLINE: In other words, clean up in the reactors in the same ways?

MR. WILLIAMS: Yes, that is what I was just talking about.

MR. KLINE: And how about work practices, are they the same pretty much in this plant?

MR. WILLIAMS: Yes, sir, these two plants keep in touch very closely and the work practices are similar as the product mix, the products that we make in the two --

MR. KLINE: Now, page 2 of your testimony, Mr. Williams, you indicate that you have an ongoing program to reduce and eliminate emissions.

Do you have a protocol that is not of a proprietory interest?

MR. WILLIAMS: No.

MR. KLINE: Do you have a protocol?

MR. WILLIAMS: I feel a little ignorant, I have been sitting here two years -- I mean five days, I am not sure what protocol means -- procedure?

MR. KLINE: Yes, sort of a game plan.

MR. WILLIAMS: Would you restate your question with

the word procedure?

MR. KLINE: Consider it restated.

Yes, do you have some type of a procedure set up, a written sort of a procedure and game plan as to when X, Y and Z are going to occur?

MR. WILLIAMS: As far as work practices are concerned?

MR. KLINE: And engineering controls.

MR. WILLIAMS: For work practices there is a detailed safety checklist, I guess you would say, of every job that is hazardous or not hazardous.

This is usually both for training personnel and reviewing older operators.

MR. KLINE: Could you make that available to us please?

MR. WILLIAMS: It is about that thick (indicating). It covers every job that we do in our plant.

MR. KLINE: Well, only with respect to those job classifications that would have potential exposure to vinyl chloride.

MR. WILLIAMS: I would prefer not to. I believe there is in the procedures much proprietary information.

MR. KLINE: Now, I take it that in recent months you have substantially reduced your level in exposure to PVC.

Could you tell us the engineering controls that you have instituted and the work practices which you instituted at each of the plants in order to reduce the level, please?

MR. WILLIAMS: As I mentioned, many of these were started last year. It is kind of hard to break out the list that would have been done in the last few months, and what has been done in the last year.

So I will just mention some of them. Some of them are long-term projects or just not being completed, but one would be relocating process plants into non-occupied areas. This is not a reproduction. It is a relocation.

The significance, I think, in reducing personal expoaure is just operator awareness, operator training, that there is a problem with inhalation of vinyl, so stand upwind instead of downwind when you are doing the job.

I think this means a lot.

We significantly modified our reactor injury procedures. And by that I mean we have put in the hands of the operators better instruments. For many years, the only instruments that they had to check that a vessel was clear of vinyl was -- was similar exposure meter.

Now, they have instruments that can tell what the level is, and you can really control the -- give them a number that is meaningful to them.

I think that is significant.

We have also -- we have installed at Delaware City and are installing at Deer Park improved reactor emergency equipment, better reaction of the reactors, before, during, before entry and during the time that the man is in the reactor.

We are a licensee of the B. F. Goodrich hydraulic cleaning system, which is about one-third of our total facility at this moment, and will be in by the end of 1974.

Do you want some more?

MR. KLINE: Please.

MR. WILLIAMS: We have done quite a bit in vapor recovery systems. Much of this was at the -- I guess you would say insistence of the Texas Air Control Board instead of OSHA, but there have been reductions in general emissions.

We have added new gas hosers for recovery systems. We have added new compressors. We have added new condensers. We have replaced some compressors with more dependable

compressors, a periodic problem that we have had is, I think, changing filters. This is a weekly occurrence, and that is now in the recovery system and hooked up to the compressor to evacuate before the man can remove the cover.

One thing that I consider significant, and it is, in a way, brought out in some of the other parts of my testimony, is improved control ventilation.

This is another OSHA requirement on pressurization of equipment.

We are just going through that.

We have very low levels in our control range where, of course, the -- as much time as possible, since it is air conditioned and it is important from our side.

As far as real quick things we have done in the last three months, we knew of some problem areas and built real quickly galvanized hoods for these pieces of equipment. And in the non-occupied areas.

These things like that have been very significant in the reductions that we have made over the last few months.

MR. KLINE: Do you have the centrifugal forces to help prevent leaks in your system?

MR. WILLIAMS: The centrifugal pressures that Dow was talking about?

MR. KLINE: Yes.

MR. WILLIAMS: No, ours are not centrifugal.

We did have two reciprocating ones that were a problem and placed it with the main types of pressures.

MR. KLINE: Let us talk for a brief moment about respirators.

You talked about use of respirators for short durations with significant VC concentrations.

The first question is, what do you consider short duration?

MR. WILLIAMS: In our Delaware City plant right now, we have perhaps 25 percent of our people in respirators for a minor part of the day, somewhat less in Deer Park.

To me, a significant length of time would be over a couple of hours, I would think.

MR. KLINE: Do your employees presently wear respirators for, say, a couple of hours, two or three hours?

MR. WILLIAMS: Yes.

It is not continuous, but they wear it, say, 15 minutes this hour and maybe 15 minutes the next hour. Maybe it works up to two hours on some of the worst situations.

MR. KLINE: And in terms of respirators, what would you consider to be a significant VC concentration that would trigger the wearing of a respirator?

MR. WILLIAMS: Whatever you set the standards at.

MR. KLINE: Are there any places in either of your plants where you have no detectable level?

MR. WILLIAMS: Define no detectable.

MR. KLINE: Plus -- one part per million plus or minus 50 percent.

MR. WILLIAMS: Would anything less than that one part per million be undetectable?

MR. KLINE: I thought I was supposed to ask the questions.

MR. WILLIAMS: Assuming that is what you meant, I think I briefly mentioned, as I was going through my data, that between the two plants, 20 percent of our readings are less than one part per million.

MR. KLINE: Are there general areas that are pretty much consistently below one point, and could you just briefly identify those?

MR. WILLIAMS: Control -- office buildings, labs, the general work areas -- I meant the general non-work areas. The yard, the maintenance shops are less than one part per million.

Warehousing is usually less than one part per million, I believe. I would have to look at the data to be sure.

MR. KLINE: Let us talk about canisters for a moment.

Do you have confidence in them as a means of protection against vinyl chloride?

MR. WILLIAMS: I am confident that they remove the vinyl.

My only difficulty with the canisters is the no

MR. CONNOLLY: Mr. Connors, if your plant in Texas would be in a position not to have to make any changes, assuming that the OSHA standards was set at 10, pursuant to the SPI proposal, but your plant in Delaware would have to make the changes to get down to any given level than they end up, would your profitability proportionately increase in Texas in comparison to Delaware as a result of not having to expend the money in Texas?

MR. CONNORS: Well, that is a pretty tough question to answer, because there are so many factors involved.

I mean, if everything were equal, which is not, and we have to spend additional dollars for capital improvement in one plant and not in another, obviously that would change the picture somewhat.

If you were, as I say, if everything were perfectly legal, which I guess is what you really want me to assume --

MR. CONNOLLY: Can you anticipate any factors that might be added into your decision-making process that would change your answer?

MR. CONNORS: I don't think so.

MR. CONNOLLY: Let us assume for the sake of argument, then, that you did not own your plant in Delaware. It was owned by another company, and that company had to expend the money and you did not have to expend the money in Texas.

Would you thereby gain some kind of competitive

advantage by not having to expend the money in Texas, whereas your competitor had to expend the money in Delaware?

MR. CONNORS: Well, again, if we put a plant in Delaware and didn't -- could keep our second plant nearer the markets, we thought that had certain advantages. We paid a certain price for that at the time, building for cold water, but what we knew about cold water at that time, we had to spend additional dollars for the same investment in the south, t[illegible] something more.

So, obviously, someone has to build a plant in the north for many reasons, and this is another one, will have to spend more money per pound of production.

This might affect his profitability unless he had some offsetting advantages.

MR. CONNOLLY: So that the general conclusion, would it be safe to say that those companies that are predominantly in the south would gain competitive advantages against those companies that are predominantly located in the north as a result of any OSHA standards?

MR. CONNORS: I wouldn't agree with that categorically.

MR. CONNOLLY: Do you think that the likelihood is great that that would be the case?

MR. CONNORS: It is too broad a statement. I would have to fall back on what I said before.

MR. CONNOLLY: Did you consider any factors that

might not make that statement be true?

MR. CONNORS: Other economic and market factors could still give someone -- I have already stated that everything being equal, you would have to spend more money to build the same kind of plant in the north, and vinyl chloride exposure would be one additional cost factor.

It could hurt everything, being equal. Everything is not always equal.

MR. CONNOLLY: All right.

Thank you very much, sir.

JUDGE MYATT: Any other questions?

(No response.)

JUDGE MYATT: All right.

Gentlemen, thank you.

Let me announce at this time some of our plans.

A number of companies have requested that they be allowed to appear, beginning July 8th, which is why we went to Diamond Shamrock and skipped over B. F. Goodrich.

Johns-Manville and Calgon also are going to appear on July 8.

A number of others have submitted their written reports for the record which we are going to designate before this hearing concludes, not this evening, but before it does finally conclude.

As I indicated to you yesterday, my intention was to

Ex. 26

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Before the

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Proposed Standard)
)
on Vinyl Chloride) Docket OSH - 36

OBJECTIONS OF BRUNSWICK CORPORATION
TO PROPOSED STANDARD

My name is Edgar Vanneman, Jr. I reside at 715 Monticello Place, Evanston, Illinois. I am the General Attorney of Brunswick Corporation, a Delaware Corporation, with offices at 1 Brunswick Plaza, Skokie, Illinois 60076. We respectfully submit the following objections to the proposed standard as published in 39 Fed. Reg. 16896-16900 and as explained in the Draft Environmental Impact Statement released June 12, 1974.

Brunswick Corporation does not manufacture vinyl chloride, but it does purchase annually in excess of $500,000 of polyvinyl chloride for use in the manufacture primarily of various essential medical products such as catheters and surgical tubing as well as other products.

I. THE PROPOSED STANDARD DOES NOT CONSIDER THE ADVERSE CONSEQUENCES TO HEALTH AND WELFARE.

Brunswick has been informed by its suppliers of finished polyvinyl chloride that the proposed standard will greatly reduce the supply

of polyvinyl chloride and that it may take several years to advance the state of the art to the point where compliance with the standard is technically feasible for vinyl chloride manufacturers.

Any standard must take into account the benefit-risk ratio. Will more persons be hurt by the standard than will benefit by it?

The essential medical products produced by Brunswick through its subsidiary, Sherwood Medical Products Inc., are critical to the health of the entire nation. As one of the leading producers of catheters and surgical tubing we know that the supply of these items to hospitals and the medical profession will be immediately shut off if we cannot get polyvinyl chloride from our suppliers. Frankly, we cannot get enough PVC to keep up with the demand from hospitals at the present time. There is simply no acceptable substitute. PVC has at least three unique properties: (1) It is thermally sensitive so that in the body it tends to relax and conform and be compatible. (2) It is the only plastic that is clear. Others are opaque in varying degrees. The surgeon and the doctor need the clear plastic in their work so that they can observe what is happening within the tubing. (3) It is soft and flexible so that it readily lends itself to manufacturing processes as well as to easier utilization by the doctor or surgeon.

We have no hesitation whatsoever in stating that the health and lives of thousands of persons will be impaired if the supply of these products is curtailed. The consequences to the public health are clearly catastrophic.

Not only will the depletion of supplies of polyvinyl chloride have an immediate, adverse affect on the many people who use our products, but of course, it will have a severe impact upon many employees whose work with Brunswick and its subsidiaries is directly devoted to such products. Unfortunately, we have no other work for these people. The impact upon the employees and their families will of course, be great.

We submit that Section 1910.93q should be revised to apply only to areas or operations in excess of 50 ppm. until such time as technological changes and advances in the state of the art permit production at lower levels or that there be different levels of compliance as suggested in these proceedings by the Society of the Plastics Industry.

II. THE APPLICABILITY OF THE STANDARD TO FINISHED PVC RESINS IS NOT CLEAR.

Section 1910.93q (a) (2) specifically states that this section does not apply to the handling or use of fabricated products made entirely or in part of polyvinyl chloride. However, there are several subsequent paragraphs of the section which mention polyvinyl chloride. Thus paragraph (d)(1)(ii), (k)(4) and (n)(1) should be stricken as they are inconsistent with (a) (2) and not justified by any evidence. The same confusion appears on pages 53 and 54 of the Draft Environmental Impact Statement.

It is respectfully submitted that the recommendations and suggestions contained herein should be incorporated in the final standard.

Edgar Vanneman, Jr.

BRUNSWICK CORPORATION

Thank you.

JUDGE MYATT: All right, the statement of the Brunswick Corporation will be included in the record as Exhibit Number 26.

(The statement of Mr. Vanneman was marked as Exhibit No. 26.)

JUDGE MYATT: Mr. Kline?

MR. KLINE: I have just a few questions, sir.

How long has the company been in business, in the business of making catheters and surgical tubing?

MR. VANNEMAN: Since about 1954, '55, something like that.

MR. KLINE: And what percentage of the catheters and surgical tubing is made of polyvinyl chloride?

MR. VANNEMAN: All of our catheters, and surgical tubing is made of PVC.

MR. KLINE: Yes. Have you investigated any substitutes for PVC?

MR. VANNEMAN: Yes, especially during the past year, when we had such a difficult time getting enough PVC to satisfy the hospitals. We have had to go to Japan and Germany.

We still can't get enough to satisfy the present demands, so our people have been looking for substitutes. As yet we have not found any.

MR. KLINE: What substitutes, briefly, have you looked into, and why have you rejected them?

MR. VANNEMAN: I cannot tell you. I think that it is because either they have the same basic problem that anything that might be forthcoming also has a petrol base, or that no one could guarantee any supplies.

But our Director of Biological Research, who has looked into these matters, and informs me that no one has suggested any of these is as yet possible. Even though they have been looking into things, he cannot tell me that any plastic will come up with the same properties that PVC has.

So he is not able to say that there is anything that will, or even suggest in what time period some company can come up with something that might.

MR. KLINE: Could you, in a post-hearing comment, indicate what substitutes your company seriously considered, and why it is that they rejected them?

MR. VANNEMAN: Yes.

MR. KLINE: I take it that you were not engaged in fabrication. You deal with the product as a semi-finished product?

MR. VANNEMAN: We take a finished pellet and extrudeat.

MR. KLINE: Thank you, I think Mr. Lanzier may have a question for you.

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MR. LASSITER: Were you present perhaps the other night when Dr. Selikoff testified?

MR. VANNEMAN: I don't recall him. I have been here most of the hearings, but I don't recall --

MR. LASSITER: He was late, about seven o'clock to eight o'clock Tuesday.

MR. VANNEMAN: No, I think I was arranging for rooming accommodations then.

MR. LASSITER: The reason I brought that up, he mentioned this same question in general that came up with him, and he mentioned some possible alternatives, and I was going to ask you what you thought about it.

MR. VANNEMAN: No, I was not aware of it.

I am delighted that there is some possibility. Did he give any time estimate?

MR. LASSITER: No, I am not sure. I thought that with your interest being here you might have known.

Do you know if your company has looked into the possibility that there may be some vinyl chloride in the tubing that might not be held in the tubing, would come off during the normal medical procedure, such as catherization, including blood transfusion, et cetera?

MR. VANNEMAN: I have -- I know that they have made tests to see whether there was any migration, and they have been satisfied with it. How extensive these are, I don't

know.

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MR. LASSITER: Okay, thank you very much.

MR. VANNEMAN: Thank you.

JUDGE MYATT: Any questions?

Yes, sir?

MR. HECKMAN: I believe that the information about Dr. Selikoff's supplies came about as a result of some questions that I asked.

If I am not mistaken, he testified as to his previous experience with glass containers for IV and blood applications. That is not the same category of product that you are discussing, is it?

MR. VANNEMAN: No, sir, there is no way that you could get a glass tube to go into the vein, or the heart, or to evacuate the lung, or do any of the other things that a catheter could.

MR. HECKMAN: Are you aware of the fact that the Food and Drug Administration has requested data from persons who package in PVC, and use medical devices made of PVC --

MR. VANNEMAN: Yes.

MR. HECKMAN: That data be supplied to show that there is no migration of vinyl polymer from PVC products, such as the ones you make into wards, so that hazards can be prevented?

MR. VANNEMAN: Right.

MR. HECKMAN: Are you aware that such data has been presented?

MR. VANDEMAN: Yes.

MR. HECKMAN: To the best of your knowledge, does all that data indicate that there is no problem in that respect?

MR. VANDEMAN: That is correct.

MR. HECKMAN: Thank you very much.

JUDGE MYATT: Are there any other questions from the floor?

(No response.)

JUDGE MYATT: Thank you.

All right, ladies and gentlemen, we are adjourning until July 8.

(Whereupon, at 5:35 o'clock, p.m., the hearing in the above-entitled matter was adjourned, to reconvene at 9:00 a.m., Monday, July 8, 1974.)

- - -

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BRUNSWICK CORPORATION
ONE BRUNSWICK PLAZA
SKOKIE, ILLINOIS 60076
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ROBERT J. DONAHUE
HAROLD POTTS
DONALD C. FELIX
JAMES R. KAY
ATTORNEYS

July 11, 1974

Ms. Jorene Cogdell
Attn: Docket OSH - 36
Occupational Safety and Health Administration
1726 M Street, N.W.
Room 200
U. S. Department of Labor
Washington, D. C. 20210

Dear Ms. Cogdell:

At the hearing on [illegible] chloride on [illegible] called by the Secretary of Labor to [illegible] to [illegible] concerning the availability of [illegible] substitutes for polyvinyl chloride.

Attached is the statement in response to that request. I would appreciate your making that statement a part of the record as requested by the Department of Labor.

Cordially,

Edgar Field, Jr.

Encl.

Before the

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

In re:

Proposed Standard)
)
on Vinyl Chloride) Docket OSH - 36

SUPPLEMENTAL STATEMENT OF BRUNSWICK CORPORATION

Now comes Brunswick Corporation by Edgar Vanneman, Jr., its General Attorney, and for its Supplemental Statement herein says as follows:

During our testimony on June 28, 1974 we were asked by the Department of Labor to submit additional information on our efforts to obtain substitution for polyvinyl chloride for our essential medical products which are used by hospitals and physicians. Our subsidiary, Sherwood Medical Industries Inc., has had a special project for the past two years to search for acceptable substitutes for polyvinyl chloride because of the [illegible] difficulty of obtaining a sufficient supply of [illegible] vinyl chloride. A number of substitutes which have been and are still being investigated include silicones, polyethylene, ethylene vinyl acetate and thermoplastic rubbers. Certain hybrid materials

have also been tested, such as silicone polycarbonate experimental resins.

We have contacted over twenty manufacturers of these materials to solicit their help and we have experimented with the various products of these manufacturers in an effort to find an acceptable substitute. To date there is no acceptable substitute.

The silicones are thermally insensitive and are not clear. The tubes we have been experimenting with are too soft to start with so that the surgeon cannot place them in the body with the facility required. It is not an adaptable to manufacturing processes such as polyvinyl chloride and does not appear to be utilizable for the sophisticated catheters required by the medical profession. We currently have a pilot plant which has been trying to utilize silicones. Silicones are not an acceptable substitute for polyvinyl chloride. In addition, silicones cost about ten times more than polyvinyl chloride and this would greatly increase the cost of health care to patients.

We have tried several hundred types of urethane tubes in an effort to experiment with them and their materials. Urethane is much [illegible] to work with than polyvinyl chloride and does not [illegible] the necessary [illegible] required to [illegible] these products. Urethane, of course, is not clear and [illegible] urethane tube for polyvinyl chloride. It is

not as sensitive to temperature and therefore is not an acceptable substitute for this reason as well). Finally, recent articles indicate that there may be problems because of the curatives used in urethane and that they may be carcinogenic. It should also be mentioned that the power consumption required to utilize urethane is much greater than for polyvinyl chloride and we simply cannot get this amount of additional energy in any of our existing plants.

Similar experiments have been made by our research laboratories with ethylene vinyl acetate. While some of these are clear, this material simply cannot be processed or fabricated with the facility required to make the sophisticated tubing required by the medical profession. It is not an acceptable substitute for polyvinyl chloride.

Thermoplastic rubbers are all opaque and do not possess the necessary clarity. They are not as heat sensitive as polyvinyl chloride. Finally, little is known as to the body compatibility of these products. As with all medical products, of course, we cannot utilize them until all possible effects of their use have been tested for a period of years on humans as well as animals. The result, the widely [illegible] to be acceptable substitutes for polyvinyl chloride.

In conclusion, we may state that we have expended a great deal of time and effort in attempting to find an acceptable substitute. In addition to our own laboratory efforts we also continue to explore all new literature and to contact our competition who have similar problems in obtaining enough polyvinyl chloride at the present time. Any curtailment of the supply of polyvinyl chloride to us will have an immediate adverse effect on the health of thousands of people who need these products.

Respectfully submitted,

BRUNSWICK CORPORATION

By _____
Robert W. Hahn, Jr.,
General Attorney

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PROCEEDINGS

JUDGE MYATT: The hearings are resumed.

Ladies and gentlemen, we apologize, or I apologize to you for the delay. However, we are ready to go forward with all dispatch.

I understand from the Solicitor's Office that they have a preliminary statement they would like to make at this point.

After their statement the first company on the list is the B. F. Goodrich Company.

MR. BOYD: I am Dan Boyd from the Office of Standards.

A question has arisen as to the relationship between the draft environmental impact statement, which I believe is Exhibit 8, and the final standard.

Let me say that this draft, like all other drafts, is a tentative document; that is the facts and conclusions set forth therein will be reexamined in light of the comments regarding the draft, the evidence adduced at this hearing and all other relevant evidence so that the final environmental impact statement will have a benefit of your input.

JUDGE MYATT: Yes, sir?

MR. CONNOLLY: Are you saying, Mr. Boyd, that the statement in the environmental impact statement, the changes that are proposed are economically and technologically feasible as a tentative conclusion?

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MR. BOYD: Sure, I think you can say everything in that draft statement, Mr. Connolly, is a tentative conclusion until it becomes a final statement.

MR. CONNOLLY: As I understand it, though, you have not based that tentative conclusion on any facts or analyses as of this juncture, is that not correct?

MR. BOYD: I think it is fair to say that when that statement was written it was based on the best available evidence that we had at the time.

MR. CONNOLLY: And you had, as I recall, from your first statement, testimony in response to a number of questions where you indicated the Department of Labor has done no engineering, technological or economic studies as of that time.

MR. BOYD: That is true.

MR. CONNOLLY: Is that true as of today?

MR. BOYD: Yes, it is.

MR. CONNOLLY: Thank you.

MR. TOPOL: Might I raise one other question for clarification, Mr. Boyd?

On the letter of June 17 accompanying the impact statement that said comments should be submitted by July 17, would it be fair to conclude that to the extent any interested party testified at this hearing, that that testimony will be considered as its comments to the environmental impact statement?

JUDGE MYATT: Anyone else?

MR. CONNOLLY: You indicated relative to the studies of those seven plants that there were no economic, technological or engineering studies done at those plants, and the same information you relied on for purposes of environmental impact statement were relied upon for the memorandum that your office put out relative to that study.

Now, did you, or did you not do any economic, technological or engineering studies?

MR. BOYD: A formal study, no.

MR. CONNOLLY: Okay, thank you very much.

JUDGE MYATT: All right, we are ready to proceed with the B. F. Goodrich people.

Gentlemen, proceed.

STATEMENT OF JOHN L. NELSON, VICE PRESIDENT-MANUFACTURING, B. F. GOODRICH CHEMICAL COMPANY: ACCOMPANIED BY MR. ANTON VITTONE, PRESIDENT, B. F. GOODRICH CHEMICAL COMPANY; MR. PHILIP J. WEAVER, DIRECTOR OF INDUSTRY AFFAIRS, B. F. GOODRICH CHEMICAL COMPANY; DR. ROGER W. STRASSBURG, DIRECTOR OF ENVIRONMENTAL AFFAIRS, THE B. F. GOODRICH COMPANY; AND DR. MAURICE H. JOHNSON, DIRECTOR OF ENVIRONMENTAL HEALTH, THE B. F. GOODRICH COMPANY; AND DR. CONDICT MOORE, PROFESSOR OF SURGERY AND DIRECTOR OF THE CANCER CENTER, UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE, LOUISVILLE, KENTUCKY

Statement of Dr. Condict Moore
Professor of Surgery
and
Director, Cancer Center
University of Louisville School of Medicine
Prepared For
Presentation At
Department of Labor Hearings On
Vinyl Chloride, Occupational Exposure Standard
June 25, 1974

My name is Dr. Condict Moore. I am a Professor of Surgery and the Director of the Cancer Center at the University of Louisville School of Medicine.

I received my B. A. from Princeton and my M. D. from Columbia University. I served my internship in Methodist Hospital in Brooklyn 1942-1943.

Following service in the United States Navy, 1943-1946, I completed residencies in:

St. Luke Hospital, New York City (Pathology) 1946-1947

Methodist Hospital, Brooklyn (Surgery) 1947-1949

Memorial Hospital, New York (Resident & Fellow in Surgery) 1949-1952

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I was certified by the American Board of Surgery in 1952 and, that same year, joined the faculty of the University of Louisville School of Medicine. Following a series of appointments at the Medical School relating to Pathology, Tumors, Cancer, and Surgery, I was made full Professor of Surgery (Oncology) in 1969. In addition, in 1972 I was appointed Director, Cancer Center, University of Louisville Health Science Center. My complete Curriculum Vitae is attached.

For the past two years a group of senior faculty members of the School of Medicine at the University of Louisville has been organizing the Cancer Center as a new interdepartmental, multidisciplinary organizational unit and functional focus of effort within the faculty of the University. This Cancer Center effort has gained much impetus from a historically strong University effort in the cancer field and from considerable consultative and financial support from the Cancer Centers office of the National Cancer Institute. The Cancer Center has begun an effective direction of effort, created a productive unit among the various faculties and schools of the University that has mobilized many different disciplines and enabled them to mount multi-departmental approaches to various specific tasks, both in terms of clinical and research cancer matters.

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When, in January and February of this year (1974), it became apparent that the relatively large numbers of cases of angiosarcoma of the liver discovered in Louisville PVC workers of B. F. Goodrich would demand considerable clinical care and consultation and research investigation, the director of the Cancer Center and the Cancer Center Steering Committee made some inquiries of Dr. John Creech, B. F. Goodrich Plant Physician, and Dr. Laszlo Makk, pathologist at St. Anthony Hospital, Louisville, Kentucky, who had been handling the clinical management of the affected workers. These inquiries were aimed at finding whether the University Medical School could be of help in any consultative or investigative way to the medical department of the B. F. Goodrich plant in Louisville. This struck a responsive chord, since Dr. Creech had been exploring with representatives of the Company the various possibilities of obtaining expert consultation and help in pursuing, managing and studying the problem which appeared to be of industry-wide and nationwide importance. Thus the two organizations, simultaneously, mutually sought out each other. The University was seeking to carry out its responsibilities for community health as well as seeking support for much needed research; the B. F. Goodrich Company was looking for clinical assistance and sophisticated scientific and academic guidance in medical surveillance and in medical consultation. Therefore, an agreement was reached within several weeks whereby the B. F. Goodrich Company would supply the University with funds through the Cancer Center organization to carry out a three-point program over a period of one year to eighteen months. The three points of this program consist of the following:

1. A medical surveillance program in which a clinical team from the University would formally screen, with specially designed questionnaires and complete physical examinations, all employees of the B.F.Goodrich plant, under the supervision of a new, unique specialist, a hapatologist, who would be added to the faculty to be the director of the program. With his help a revised protocol of laboratory testing would be instituted on all employees. Medical consultation and help would be provided from a panel of university specialists whenever required.

We are particularly interested in developing an improved protocol, since there has been consensus here and in the medical community that the current protocol is simply not discriminating enough nor sufficiently predictive.

As a further protocol problem, Dr. Johnson has informed us that Goodrich, in applying the SMA 12 to young applicants for employment, the test rejects an abnormally high number of young people who obviously are generally healthy and have had no VCM exposure.

2. The second area of commitment consists in establishing, with the help of a new epidemiologist and staff, a registry for all cases of diagnosed or suspected vinyl chloride-associated disease occurring at the plant in Louisville, a registry designed with the capability of being expanded throughout the industry, and open to participation by other companies.
3. The third part of the agreement was that the University would begin a University-wide, basic research program designed to study the toxic and disease-producing effects of vinyl chloride and related compounds, a program to be monitored by intramural and extramural scientific review committees.

In short, we are addressing ourselves to finding out what vinyl chloride and related compounds will do to the human body, how we can predict pathological effects, how we can properly take care of people who have already had disease-producing exposures, and how to prevent other workers from getting a dangerous level of exposure.

The agreement was signed within the past month. Progress to date has consisted of the appointment of an outstanding hepatologist who will be on site within two months and who will make periodic visits within the next two months to help organize the program without delay. A team of clinicians has been formed and plans have been made in the medical department of the Louisville plant of the B. F. Goodrich Co. to perform physicals and complete medical histories, and special questionnaires on all employees beginning July 1. This special clinical study should be completed by the middle of August. Input into the design of the questionnaire and the physical examination has been secured from numerous individuals in a variety of disciplines both within the institution and from the outside. Contact has been made with the several national and federal agencies interested in this problem, including the National Cancer Institute, NIOSH, and EPA. Representatives of these organizations have visited Louisville and been apprised of our plans. The long-range aspect of this program is periodic re-examination, re-study and careful follow-up on all previous, present and future employees. In the area of registry establishment,

a person accomplished in epidemiology and biostatistics has been employed to begin work by the end of July in the design of various studies. In this regard we plan to draw upon the talents of Dr. E. Cuyler Hammond, Vice President and epidemiologist-statistician of the American Cancer Society in New York City, who has agreed to be consultant to our program. He has visited Louisville and consulted at length with company statisticians and with our multidisciplinary groups at the University.

In the area of basic research, 17 research proposals have been received and reviewed by special survey and review committees within the University. After a series of critical analyses, seven proposals have been funded at relatively low levels of funding to stimulate small pilot studies in the approved areas of research. We hope these will lead to larger studies with funding from other sources within the next year. These projects include the study of the value of electron spin resonance variations in detecting angiosarcoma and other changes in tissues exposed to vinyl chloride; the possible interaction between vinyl chloride and viral RNA or reverse transcriptase; electron microscopic studies of diseased liver tissue available to the University research group; measurements of sinus blood flow and Kuppfer cell function as a possible guide to early liver damage and malignant transformation; liver-specific studies looking for these as indicators of chronic vinyl chloride exposure; and the use of mutagenicity experiments to indicate carcinogenicity of vinyl chloride and its related compounds or their metabolites.

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We expect to have most aspects of this three-part program fully under way within the next year; that is, thorough, formal medical screening of all of the employees of the B. F. Goodrich plant in Louisville, a skeleton registry of vinyl chloride-exposed individuals begun so that it can be expanded and added to, and some indication of which pilot studies in basic research are worthy of further larger funding and more intensive pursuit in the laboratory.

CURRICULUM VITAE

CONDICT MOORE, M.D.

1975

Date and Place of Birth: April 29, 1916 Essex Fells, New Jersey

Marital Status: Married

Education:	B.A.	Princeton University, Princeton, N.J.	1938
	M.D.	Columbia University College of Physicians and Surgeons	1942
Internship:		Methodist Hospital, Brooklyn, New York	1942-1943
Residencies:		St. Luke Hospital, New York City (Pathology)	1946-1947
		Methodist Hospital, Brooklyn, New York (Surgery)	1947-1949
		Memorial Hospital, New York (Resident and Fellow in Surgery)	1949-1952
Military Service:			
		Lt. (j.g.) and Lt., U.S.N.R.	1943-1946
Certification:			
		American Board of Surgery	1952
Hospital Appointments:			
		Active Staff: Louisville General and Norton-Children's Hospitals, Louisville, Kentucky	1952-
		Courtesy Staff: Kentucky Baptist, St. Anthony, Jewish and Methodist Hospitals, and St. Joseph Infirmary	1952-
		Consultant in Surgery: Veterans Adm. Hospital	1969-
Academic Appointments:			
		Instructor in Surgery (clinical), University of Louisville School of Medicine, Louisville, Kentucky	1952-1958
		Director of Tumor Clinic, Univ. of Louisville and Louisville General Hospital	1952-
		Assistant Prof. of Surgery, Univ. of Louisville School of Med. (in charge of cancer training)	1958-1961
		Associate Clinical Professor of Surgery, Univ. of Louisville School of Med. (Cancer Teaching)	1961-1969
		Associate in Pathology, Univ. of Louisville School of Medicine, Louisville, Kentucky	1962-
		Professor of Surgery (Oncology), Univ. of Louisville School of Med., Louisville, Kentucky	1969-
		Director, Cancer Center, University of Louisville Health Sciences Center, Louisville, Kentucky	1972-
		Director, Breast Cancer Screening Project University of Louisville	1973-

CURRICULUM VITAE

CONDICT MOORE, M.D.

Professional Activities:

Founder and Director Oral Cancer Diagnostic Clinic, University of Louisville School of Medicine Louisville, Kentucky	1965-
Director, Clinical Cancer Training Program, University of Louisville School of Medicine	1965-
Consultant in Chronic Disease Kentucky State Department of Health (Cancer)	1955-1958
Chairman, Cancer Coordinating Committee Kentucky Medical Society	1960-1965
Chairman, Cancer Liaison Fellows for Kentucky American College of Surgeons	1970-
Member, American Association for Cancer Education	1967-
Member, Breast Cancer Task Force, Committee on Diagnosis, National Cancer Institute, NIH HEW	1972-
Member, National Surgical Adjuvant Breast Project Pittsburgh, Pennsylvania	1973-

Professional Societies:

American Radium Society
American College of Surgeons
American Cancer Society - Kentucky Division
Director
James Ewing Society
Society of Head and Neck Surgeons, Founding Member, Vice-President (1974)
Southern Surgical Association
American Medical Association
Kentucky Surgical Society
Kentucky Medical Association
Cancer Committee
Louisville Surgical Society (Pres., 1965)

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Consultant - Year Book of Cancer publications.

concerns fundamental process improvements to reduce losses inherent in our present processes.

To our knowledge, there is no PVC production plant in the world operating in a completely closed polymerizer mode because of the buildup problem in reactors.

Our programs toward this end include investigations of the fundamental mechanisms leading to resin adherence to polymerizer surfaces and a wide variety of methods aimed at eliminating adherence, chemically and/or mechanically. It is difficult to estimate how soon, if ever, we might achieve our goals in a practical way.

The balance of our research and development program includes reduction of monomer losses beyond the polymerization area. This is the development of a process by which the vinyl chloride monomer is removed from the PVC resin slurry before drying, thus increasing the recovery of vinyl chloride monomer.

This would also result in lower residual vinyl chloride in our finished resins when proven in production plant installations. We can foresee completion of this work and installation of facilities in two to four years for the majority of our resins.

Finally, in order to reach levels below .01 percent residual vinyl chloride in some PVC resins, we see the necessity for some basic changes in our manufacturing technology and the structure of PVC particles. This will take time to complete

the small-scale work and scale up to production facilities.

Goodrich position -- Goodrich believes it prudent to reduce levels of exposure to vinyl chloride,,but opposes the proposed permanent standard for vinyl chloride. Achievement of no-detectable level of VCM exposure is not technically feasible. Neither is it feasible nor safe to require VCM and PVC workers to wear respiratory protection for ~~full~~ full eight hour work shigts. Thus, if the proposed standard is adopted, Goodrich would have no alternative but to shut down its monomer and PVC resin operations.

Goodrich generally supports the position outlined by witnesses for the Society of the Plastics Industry.

Exposure levels -- more specifically, we endorse the SPI proposal on the stepwise reduction of vinyl chloride levels in PVC work areas and in vinyl chloride monomer work areas.

Further, Goodrich is committed to reach these levels of exposure in the shortest practical time. As evidence of our commitment, before OSHA issued the proposed permanent standard, we set an internal goal of achieving a 25 ppm ceiling and 10 ppm TWA as soon as possible.

Monitoring -- the standard should require sequential monitoring of work areas in both monomer and polymer plants with proper alarms to signal the need for respiratory protection. This should be backed up with adequate personnel monitoring to validate the area monitoring system.

Respiratory protection -- We support the SPI recommendation that OSHA give management the necessary flexibility to select and utilize the most appropriate respiratory equipment for the protection of workers. This could include the use of half-face air-purifying type protection.

Impervious clothing -- We urge OSHA to reconsider the requirements covering the use of impervious clothing. Others have previously testified that such clothing presents a serious restraint on worker mobility. It also exposes the wearer to severe heat stress, particularly when worn in confined areas and where physical effort is required on the work assignment.

There may be some occasions where high exposure levels can occur. In those instances, suits impervious to water should be adequate. But for most jobs in vinyl chloride monomer and polyvinyl chloride plants, including reactor cleaning, where exposure is at low levels, regular work type clothes (coveralls or pants and shirts with full length sleeves) should be adequate.

Vinyl chloride level in PVC -- Goodrich supports the SPI proposal that appropriate lebeling of PVC containers be required when vinyl chloride levels in PVC exceeds 0.1 percent, effective October 5, 1974, and further, that the requirement for labeling be changed to 0.01 percent effective October 5, 1977.

Labeling -- We support the SPI position that the

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language to be used on signs at regulated areas emphasize the precautionary steps to be taken, rather than "scare" language emphasizing the nature of the substance.

Similarly, we support the SPI concept of product labeling, both monomer and polymer, and agree that such labeling should be designed to provide information to those who need it, rather than a basis upon which to panic because of a potential disease characterization.

As part of our overall effort, on about May 1, 1974, Goodrich made a grant to the University of Louisville Medical School Cancer Center. This was the result of Goodrich's desire to bring continuing comprehensive medical advice and consultation to the situation and to support a broad scientific inquiry into the problem.

At this time, I present Dr. Condict Moore, Professor of Surgery at the University of Luisville School of Medicine, who will summarize the program which the University is initiating pursuant to a grant from Goodrich. Dr. Moore's statement is attached. When he concludes his testimony, I will make a summary statement.

DR. MOORE: My name is Dr. Condict Moore. I am a Professor of Surgery and the Director of the Cancer Center at the University of Louisville School of Medicine.

I received a B. A. from Princeton and my M. D. from Columbia University. I served my internship in Methodist Hospital in Brooklyn 1942-1943.

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6. We oppose the permanent standard as proposed by OSHA, and generally endorse the position taken by witnesses for the SPI.

7. We will support and cooperate with programs to obtain medical and toxicological data that are needed.

JUDGE MYATT: Thank you, gentlemen.

Mr. Kline?

MR. KLINE: Gentlemen, I would like to say we appreciate your coming to us with some cold hard facts.

I notice that the statistics which you gave us in terms of exposure were general statistics covering all of your plants.

Would it be possible for you to supply to us in terms of job classifications at each plant what the exposure might be?

MR. WELSCH: Speaking of the EWA type data?

MR. KLINE: Yes, I believe it is Exhibit 2, Exhibit 3, right.

MR. ERLOCH: This is, as I indicated in our testimony, a relatively new operation. We have only done this for two months. The data available is rather limited.

We do have more than we have supplied here, but it is pretty preliminary.

MR. KLINE: Well, do you think in a post-hearing comment you might be able to supply the information in the form

contacted angiosarcoma ever passed out, or reported dizziness as a result of exposure to vinyl chloride?

MR. NELSON: Our records would indicate that they did not, or were not exposed to exposures of that level.

MR. KLINE: Do you know what percentage of your leaks are fugitive leaks?

MR. NELSON: No, there is no way of estimating any amount of fugitive leaks.

MR. KLINE: Are there leaks which are too small to be picked up by the OVA?

MR. NELSON: The OVA is a relatively sensitive instrument.

If the probism is placed close enough to the source of a leak you are going to get an indication of a leak.

MR. KLINE: Now, I take it that employees who clean vessels wear respirators, is that correct?

MR. NELSON: Yes.

MR. KLINE: And are they air line respirators?

MR. NELSON: Yes, they are.

MR. KLINE: I take it you have had no accidents as a result of the hoses, et cetera, or have you?

MR. NELSON: Not to my knowledge.

MR. KLINE: How long have employees been wearing air line respirators in cleaning the reactor?

MR. NELSON: Since early this year.

MR. KLINE: Do they wear any special type of clothing?

MR. NELSON: They wear impervious suits over their work clothes. We are using two different types, both of which are disposable. They are worn several times, and then thrown away.

MR. KLINE: Directing your attention to page five of your testimony, please, you have estimated the prior exposure level at between 200 and 500 parts per million.

Is that based upon your judgment as people who have been involved in the field, or is it more to it than that?

MR. NELSON: We have here a fragmentary data taken over the years, but based more upon interviews with employees who were vessel cleaners at that point in time, based on their indication of when they could smell vinyl chloride, and when they might be dizzy from vinyl chloride, or based on exposure meter level.

MR. KLINE: In the next paragraph you indicate that 100 times today's emergency standard, 200 and 500 parts per million, is that a time-weighted average, the 5,000 excursion level in your estimate?

MR. NELSON: We say peak exposure levels ten and 20 years ago were 100 times [illegible]'s emergency standard.

This is derived by the fact that there is enough intoxicating effect in about 500 parts per million, which is 100 times the emergency standard.

MR. KLINE: Now, when you interview the employees to determine what the level might be, did you take any notes, or keep any records about those interviews?

MR. NELSON: I didn't do the interviewing.

MR. KLINE: Do you know whether the person who did the interviewing took any notes on that?

MR. NELSON: I expect he did.

MR. KLINE: Would you be able to make that information available to us in a post-hearing comment?

MR. NELSON: If it is available we can.

MR. KLINE: Thank you.

Why would some processes require cleaning after every batch, and some not require cleaning after every batch?

MR. NELSON: We make several dozen types of PVC resins. The designs are custom tailored to specific customer needs. These have various polymerization cycles, times and recipes, and equipment, so that the amount of buildup left in a vessel after cleaning varies with the type of product we make.

MR. KLINE: Which processes leave the greatest buildup in a reactor?

MR. NELSON: A resin which is relatively new with us that has a high voracity.

MR. KLINE: Is that licensed, that in the name, or can you tell us?

MR. NELSON: It is a licensed process.

MR. KLINE: That means you can't tell us what the name of it is?

MR. NELSON: We sell it as G-90 and G-92.

MR. KLINE: Now, directing your attention to page six of your testimony, in the second full paragraph, you have indicated that you installed additional equipment, and later you have indicated that certain equipment, is that the sole equipment that you added to the various plants?

MR. NELSON: I am not sure which part of the page you are referring to.

MR. KLINE: In the second full paragraph, the first sentence, you indicate, and I quote:

"Concurrent with the evolution of polymerization design and recognized cleaning we installed additional equipment to improve removal of vinyl chloride from the reactor prior to entry."

Did you indicate which equipment you have added in the listing later?

MR. NELSON: This equipment is used for the purging or ventilation of a vessel prior to entry by a vessel cleaner.

The systems used went through quite an evolution over the years. The first method used was to simply fill the vessel with water to displace the vinyl chloride in the work atmosphere.

We went from that to a fan with a hose dropped to the bottom of the vessel and exhausted the vinyl chloride monomer from the vessel.

Then this has progressed to fixed installation, peak capacity fans capable of rather purging and ventilation of the vessel.

MR. KLINE: Now, directing your attention to the new plant, have you ordered the equipment for the new plant, the reactor, and the like?

MR. NELSON: With very few exceptions, all of the equipment is on order. In fact, some of it is being delivered.

MR. KLINE: What was the down time on the delivery of the reactor?

MR. NELSON: You mean the delivery time?

MR. KLINE: Yes.

MR. NELSON: I was thinking about 16 to 18 months from the placement of the order, as I recall.

MR. KLINE: Now, again directing your attention to the cold rooms, do you know what levels exist in the various cold rooms that you have in your various plants?

MR. NELSON: We take readings within the cold rooms periodically. Two of our plants have such installations.

MR. KLINE: Which plants are they?

MR. NELSON: Avon Lakes, Ohio, and Louisville, Kentucky. Entry into the rooms are only when the worker is

protected by air lines.

MR. KLINE: Do you know what tha level of exposure is in the Louisville plant in their room?

MR. NELSON: I don't have the data with me. It varies considerably.

MR. KLINE: Do you know the range?

MR. NELSON: One-hundred to several hundred ppm vinyl chloride.

MR. KLINE: Would it be imposing upon you to ask you to supply that information with respect to both the cold rooms?

MR. NELSON: We will be glad to do so.

MR. KLINE: Thank you.

MR. KLINE: Directing your attention to page 10 of your testimony, in the third paragraph: "New procedures have been implemented for opening reactor man-hole covers which reduced emission to the work area."

Would you indicate to us what those procedures are, please?

MR. NELSON: This varies with the plans, the size of the reactor, the design of the reactor that they are using and some cases we are able to connect a ventilation hose to the reactor for a slight reduction of pressure before the man-hole is opened.

In some cases it is a similar effect by holding a ventilation hose right at the man-hole opening. And in every case we are reducing the pressure into our recovery system to the limit of its availability of vinyl chloride before ventilation, before any ventilation is done and before the vessel is open.

MR. KLINE: Would it be fair to assume that these have been implemented since January of 1974?

MR. NELSON: Yes.

MR. KLINE: Have they been implemented in all of your plants?

MR. NELSON: To a greater or lesser degree they are doing all that they can with a vessel that they have.

MR. KLINE: I would like to direct your attention

to the recovery operations.

I recognize it is likely to vary from each, from plant to plant, but could you give us a general description of how the improved recovery has been attained?

MR. NELSON: How the recovery has been attained?

MR. KLINE: Yes.

MR. NELSON: There are many ways on checking this. The polymerizer contents, more temperature pressures to drive off vinyl chloride before the vessel is opened. It drives off more vinyl chloride into the recovery system, making it more available for -- in a general way we tightened up our recovery systems which includes vacuum pumps, valve stems, these kinds of things, to improve the over-all recovery on the unreacted vinyl chloride.

MR. KLINE: Has this affected the quality of your product?

MR. NELSON: There is a risk that this can happen. We have avoided deterioration of qualities, yes.

MR. KLINE: Let us talk about the man-hole exposure seals. I take it that you have put in new types of closure seals, could you describe what, why these particular seals are more effective than others?

MR. NELSON: This particular comment refers to man-hole covers on our smallest reactors.

The solution of this problem does not apply generall

to all of our polymerizer systems. But the man-hole covers in the past has been fastened down by bolting onto a lead gasket, which is subject to heat. Defamation and leakage after the vessel warms up, we have developed a nozzle which has an O ring on either side of the bar stock, formed in the shape of the man-hole cover so that the seal on both the man-hole cover and on the reactor is much more positive.

We are in the process of supplying all of our -- 100-gallon vessels with this type -- this has not been completed yet.

MR. KLINE: Now, directing your attention to page 12 of your testimony, you indicate that further improvement of automatic systems to warn of excursions.

Which systems are you talking about, and do you have them in all of your plants now?

MR. NELSON: There we have in mind a fixed Bendix type sequential monitoring by organic paper analysis.

We have this installed in all of our plants, in all of our buildings.

We have plans in mind to install a mini-computer to these systems, assuming that on a test installation it is successful.

But this then would integrate the hundreds of readings that come to the instrument and sound alarms at any determined level that we might set.

MR. KLINE: Now, in the next paragraph you talk of magnetic level indicators and you indicate that there is a down time of 18 to 24 months.

Have you actually ordered these magnetic indicator levels?

MR. NELSON: We have not yet ordered these magnetic indicators.

The request for the funds with which to do this is at hand. We are setting the the brim of petitions of installing this on tank cars that we do not own, but it is our intention to proceed with this.

MR. KLINE: Now, let us talk about your new plant.

Do you have any projections as to what the exposure levels will be, the range of the exposure levels in the new plant?

MR. NELSON: There is just no way of projecting what the exposure levels will be in this plant.

As we say in our testimony, we expect that it will be less than in our existing plants for the reasons mentioned.

MR. KLINE: Is one of the reasons why it is difficult to project that there are new engineering controls and work practices that are going to be instituted there?

MR. NELSON: Yes, that is a part of it.

We have, this will be an outdoor polymerization unit in which we have had no direct experience in the past.

All of our plants are enclosed, for all practical purposes. We are incorporating into this plant design our latest technology, we expect it will perform better, proficiency will be higher, but we won't know until the plant is shaped down in our direction.

MR. KLINE: What engineering controls are going to be put in to affect in the new plant, that are not in existence in the old plants, which will reduce the exposure level?

MR. NELSON: This plant will be computer controlled. Many of the operations now done manually on the operating floor of our PVC plant will be done by a computer from a remote location.

MR. KLINE: Can you tell us which job classifications will be involved in that, or make that available to us in post-hearing comments?

MR. NELSON: [Nodding head.]

MR. KLINE: Excuse me, please continue.

MR. NELSON: We will have improved recovery operations in the plant. We expect to utilize more of the vinyl chloride that is discharged -- less loss to the atmosphere.

In fact, in three reactors, we will be doing the work of many other 1100-gallon polymerizers. For example, it minimizes the number, the sources of leaks. As we indicated here, we expect 87 percent potential resources.

MR. KLINE: Could you indicate to us how or in what way the computer controls can reduce employee exposure or in fact eliminate the need to have employees there?

In other words, which engineering controls would reduce employee exposure?

MR. NELSON: The computer will control a charging operation; it includes the ingredients that go into the polymerizer charge.

It will completely control the operating temperature it will control the point at which the charge is blown down; it will perform also the operation necessary to polymerize batch charge, and going down without manuals at the reactor test site.

MR. KLINE: On page 14 of your testimony, you suggested that the removal of the -- the greater removal of the monomer from the slurring will take two to four years.

I would like to know how you came up with two to four years, if you can enlighten us, please.

MR. NELSON: Well, our development work so far indicates that this can be -- we are optimistic that it can be commercialized. The system for reducing monomer chloride on the surface, this has not yet been proved out in a commercial unit, and it will be about two years before we will have a commercial plant installed for the -- a demonstra-

tion plant installed to prove out what we think will happen. If it is successful, we will need several of these in our manufacturing systems, several new stripping systems across the country. All of which is going to take time to engineer, procure and install.

MR. KLINE: On page 15 of your testimony, you indicate that you have a goal of reaching 25 parts per million ceiling and ten parts per million time weighted average. I assume that is the PVC plant?

MR. NELSON: Yes.

MR. KLINE: Do you have any estimate as to when you can reach those levels?

MR. NELSON: As soon as possible.

We are working hard at it, obviously from what we said in the testimony, we are a long way from being there at this time.

We have excursion problems for which we have not found answers. This is our goal, we are working at it.

There is just no way of projecting when we will reach it.

MR. KLINE: Now, I would like to direct your attention to your current agreement with the SPI recommendation as to exposure levels.

How do you conclude that a time weighted average of 25, with excursions to 40, your PVC plants, are levels that

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can be reached?

MR. NELSON: Well, it was only recently that we have available TWA data based on personnel monitoring.

This gives us encouragement that we can meet this standard by October across our system. We are not there yet, and in many areas of our system, we are working hard to get there.

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MR. KLINE: Let me ask it this way: is there some basis upon which you have concluded that 25 ppm is obtainable at a time-weighted average with excursions of 40?

MR. NELSON: Based on the progress that we have made in the past six months, we are optimistic that we can do this. There is just no way of projecting what we can do.

But, we have a commitment, more than anything else, to achieve these levels under the date specified.

MR. KLINE: Is it possible that you could get lower than those levels?

MR. NELSON: Not with any consistency, I wouldn't think, at this time.

I suppose it is possible. This is our goal.

MR. KLINE: Let us talk about -- was it, 1976 or 1977, the lowering of that standard?

On what basis do you conclude that you can reach the lower standard.

MR. NELSON: Again, it is a projection.

We are putting some faith in our research and development efforts. We are encouraged by the progress we have made so far, and we expect to get quite a few. We might not make it.

MR. KLINE: Would it be fair to characterize that as more speculative rather than the recommendations with respect to October of this year?

MR. NELSON: Perhaps that is true.

MR. KLINE: Would it be fair to say it is possible you won't be able to reach it and it is also possible that you could get below that?

MR. NELSON: It is possible.

MR. KLINE: Now, directing your attention to the Louisville plant, will the Louisville plant be able to reach the SPI recommendation or will it have to close down?

MR. NELSON: We expect to be able to live with the standards that we have proposed for October '74, 5 and 6.

This will require these respiratory protection times, stay within the maximum specified.

MR. KLINE: I would like to direct your attention to your one modern plant.

I may have missed. Did you have any statistical data here on the monomer plant?

MR. NELSON: TWA monitoring on Exhibit 2, we showed three jobs: furnace operator VC-1, purification operator, and tank farm operator, in the range TWA data.

MR. KLINE: I take it, then, that in order to reach the recommended SPI standard, you wouldn't have to do anything to meet that, is that correct?

MR. NELSON: Well, we have some excursions beyond the proposed ceiling level.

MR. KLINE: Could you make that information

including angiosarcoma --

MR. MOORE: Yes, it would.

DR. LASSITER: Are there any other diseases that you now know of besides the tumors that you have described here, beforehand, which would be ascribed to vinyl chloride?

DR. MOORE: No, what comes to my mind is the associated peculiar fibrosis of the liver with angiosarcoma. And with other workers who, in fact, don't have angiosarcoma.

DR. LASSITER: I notice you intend to open this participation up to other companies. You probably haven't started a registry, as yet, I suppose, except, maybe, with the Louisville plant.

Have you had interest expressed to you by those other companies or have you made this available to them by public knowledge at this time, to participate in the registry?

DR. MOORE: I have not approached other companies, no, we have not standardized it and tried enough to be a model. But, approaches to other companies, no.

DR. LASSITER: But you do intend to invite them to participate as indicated?

DR. MOORE: Indeed.

DR. LASSITER: I notice that you have made contact with several federal agencies interested in the problem. Have you invited any more from OSHA to participate in the problem, and if so were we refused?

DR. MOORE: We did not invite OSHA. We have been so busy in organizing this at such short notice, but we certainly would have gotten around to it if we issued invitations.

DR. LASSITER: We do have an interest, so I am sure your invitation would be accepted.

On page 6 of your testimony, just as general information, you mentioned that seventeen research proposals were submitted, realizing that there is a lack of funding, etcetera, inherent in screening out proposals that are accepted. Could you, in general, tell us the source of these research proposals, that is, were there any from governments --

DR. MOORE: They are from our own factory.

DR. LASSITER: From Louisville Medical Center?

DR. MOORE: Yes.

DR. LASSITER: I notice, just eyeballing your areas, the project areas you intend to engage in, that you have not included anything that would be described primarily as a metabolic study, such as what valve was presented last week.

Do you intend to do any type of metabolic studies?

DR. MOORE: Yes, we do, and that is an omission because we actually have, perhaps since I wrote this up, funded another study that is a metabolic study.

DR. LASSITER: That is, it will look at metabolic pathways, etcetera?

DR. MOORE: Yes, using labor materials.

DR. LASSITER: DDo you envision that any of the tests that you have, that you are talking about here, would be useful in early warning type situations with workers who might be exposed to vinyl chloride?

DR. MOORE: Yes, I do.

I think, particularly, the liver and to general study and possibly the sinus blood flow of the functions.

DR. LASSITER: Would these be early enough to realize abnormalities, even including false policies prior to malignancies developing in the liver?

DR. MOORE: I certainly would hope so, yes, indeed.

MR. KLINE: I have one further question.

Mr. Nelson, on Exhibit 2, you have indicated that you require the wearing of a respirator at 25ppm, or when there is a risk of exceeding 25 ppm.

Why do you do that?

MR. NELSON: It is just consistent with our internal goal of reaching a 25 maximum ppm ceiling, and we are requiring respiratory protection, when the exposure does or could exceed 25 ppm to your standard --

MR. KLINE: What kind of respirators are these employees wearing?

MR. NELSON: These are cartridge type respirators, just used for brief exposures. Air fed respirators at about 25.

MR. KLINE: If the exposures -- I am sorry, I am not sure I heard you.

If the exposure is above 25?

MR. NELSON: Above 50. Air fed respirators.

DR. LASSITER: I have one more for Dr. Moore.

Much speculation is centered around the geographical distribution of the angiosarcoma deaths with the vinyl polychloride workers.

Do you have an opinion as to why more cases have occurred around the Louisville facility than have occurred elsewhere?

DR. MOORE: I just have to rely on what I was told by Dr. Creech, who has been connected with the Louisville plant, that it is the oldest of the plants, that it is still using the original technology, more or less, that was used about 1940.

The two cases that were reported in Connecticut, where the workers were not directly exposed but they were simply working in the vicinity of the plants, are simply puzzling, don't fit with the concentration that we have with the level -- I mean, if the concentration level, concentration of angiosarcoma cases was due to very, very high exposure

compensation costs would cease as a result of it, it seems that it may be relevant to the economic considerations that the secretary will be making.

MR. VITTONE: The B. F. Goodrich Company has not claimed economic feasibility in any of its presentations.

MR. KLINE: I understand that, Mr. Vittone. But I think it is relevant, not only with respect to your company, but it may give a ballpark figure as to what workmen's compensation figures in angiosarcoma are bringing these days.

JUDGE MATT: All right, gentlemen.

MR. VITTONE: I believe the question was directed at me.

I do not have the answer, except to tell you that we follow the laws of the State of Kentucky.

MR. SAMUELS: Could I ask you how much is being spent for vinyl chloride containment in that plant, and in the new plant?

MR. VITTONE: I will give you some very rough figures.

We are looking at upwards of $3 million just for ventillation and for locker rooms within our facilities.

MR. SAMUELS: Aside from workmen's compensation and other parameters, the medical economists give us the externalized cost of medical care and hospitalization.

Do you have any idea of how many claims relative to

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DR. MOORE: No, I am sorry I don't.

MR. SAMUELS: Another way of getting at it might be to ask you your recollection to the NCI cost of approximately -- for direct cost of advanced cancer patients of medium $19,054. Does that sound like it is in the ball park?

DR. MOORE: No, that must be management at an extremely inflated rate. It is just not true in Louisville. It doesn't sound reasonable for any --

MR. SAMUELS: That is all costs, even those that are absorbed by the community or training, and so forth.

DR. MOORE: Well, I can't give you an accurate answer. It sounds very, very likely.

MR. SAMUELS: Thank you.

JUDGE MYATT: Any other questions from the floor? Yes, sir?

MR. MILLER: Marshall Miller, representing Diamond Shamrock.

What is the age of your next oldest plant? I understand that Louisville is your oldest.

MR. VITTONE: The next oldest plant is a plant at Avon Lake, and I believe that was started up in 1952.

MR. MILLER: Have you been able to do the detailed health studies at that plant that you had in Louisville, or at least anything comparable?

MR. VITTONE: I think I would defer that question to

DR. JOHNSON: We started a comparable program. It is not yet completed. We just made our first run-through.

MR. MILLER: Have you had findings of angiosarcoma of the liver there?

DR. JOHNSON: No, no findings.

MR. MILLER: Do you presently have any theories or have you explored the possibility of co-carcinogens or potentiation there?

DR. JOHNSON: We certainly thought about it, although we have not been able to put our finger on anything concrete.

MR. MILLER: As I understand, for the record, you don't have any ideas why you are having a problem at Louisville plant, but not having a problem any other place in the country?

DR. JOHNSON: Not other than it has 10 years service when at a time when there was -- of the toxicity.

MR. MILLER: Thank you, very much.

JUDGE MYATT: Thank you.

Yes, sir?

MR. HECHMAN: Jerome Hechman --

JUDGE MYATT: Mr. Hechman, I am sorry, I recognized the gentleman in the back.

MR.BAUER: My name is John P. Bauer, air products and chemicals.

MR. NELSON: In response to a question from Mr. Kline earlier, you said that your reactor cleaners are now wearing impervious suits.

In response to a later question, I became slightly confused as to what you meant. The impervious suits that your men are wearing now, are they the impervious suits contemplated by the proposed standards, or are they waterproof suits?

MR. NELSON: The standard. We have been experimenting with two or three different types of clothing which are resistant to water. We don't know that they are resistant to vinyl chloride. We are experimenting with them, putting our workers in these during the cleaning operation. They are not particularly serviceable. They tear readily and offer very little in the way of protection. So, we are not satisfied with them. Nor are we satisfied with requirements for impervious clothing in a vinyl cleaning operation.

MR. BAUER: Yes, sir, what I am trying to make sure is that we understand the term "impervious" as used by both parties.

These impervious suits that you are wearing have a loose throat, a loose cuff, and are loose around the waist and pantlegs. They are not air tight suits, by any stretch of the imagination, are they?

MR. NELSON: That is correct.

MR. BAUER: Thank you. In response to another question,

you gave the delivery time of your new reactors as 16 to 18 months. Can I assume that these were ordered some time ago?

MR. NELSON: Yes, they were ordered about the third quartex of last year.

MR. BAUER: Do you have any idea what the delivery would be for equipment ordered now or in the next, maybe, six months?

MR. NELSON: At least 18 months, perhaps as long as 24 months.

MR. BAUER: Thank you, sir, that is all I have.

JUDGE MYATT: Mr. Hechman?

MR. HECHMAN: Jerome H. Hechman, General Counsel, Society of the Plastics Industry.

Mr. Vittone, I just want to be clear on B.F. Goodrich's position and, in the sense, also SPI's, and you are in a position to answer for both.

Is it not your position that the B.F. Goodrich is spending what it is spending on improving the containment situation within the limits of technical feasibility and without regard for whether or not there will be savings on such matters as workmen's compensation and that type of thing?

MR. VITTONE: That is correct. As I stated earlier, we do not claim economic feasibility. If we have the feasibility for doing it, we are doing it.

MR. HECHMAN: Are you doing everything you can do

within your technical capabilities?

MR. VITTONE: That is correct.

MR. HECHMAN: Is it your understanding also that the SPI position with respect to economic feasibility is that a tolerance should not be set that would put the industry out of business and, thereby, would create greater economic impact throughout the economy?

MR. VITTONE: That is correct.

MR. HECHMAN: And that is the basis of the economic position?

MR. VITTONE: That is correct.

MR. HECHMAN: Thank you.

JUDGE MYATT: Are there any other questions from the floor?

(No response.)

JUDGE MYATT: All right, gentlemen, thank you, very much.

By my watch, it is five after 12:00.

We will adjourn for lunch until 1:30.

(Whereupon, at 12:05 o'clock, p.m., the hearing was recessed for luncheon, to reconvene at 1:30 o'clock, p.m., the same day.)

Rubber Manufacturers Association.

RUBBER MANUFACTURERS ASSOCIATION

WILLIAM R. MILLER, DR. WILLIAM T. WICKAM, DENNIS HARKUSSON, DR. C. W. WADELIN, DR. WALTER HARRIS, AND FRANK T. RYAN

MR. MILLER: Judge Hyatt, I am William R. Miller, Manager of Corporate Safety and Workmen's Compensation Administration for the Goodyear Tire & Rubber Company in Akron Ohio, and Chairman of the Occupational Safety and Health Committee for the Rubber Manufacturers Association, often referred to as the RMA.

I am accompanied by the following industry representatives who will assist in answering any technical and/or legal questions: Dr. William T. Wickam, to my immediate rear here, Vice-President of Research and Development of the Dayco Corporation from Dayton Ohio; Mr. Dennis Markusson, Assistant Counsel for the General Tire & Rubber Company in Akron, Ohio, sitting next to him in the back; and Dr. C. W. Wadelin, to my immediate left here, Section Head, Research Department of the Goodyear Tire & Rubber Company in Akron, Ohio; to my immediate left is Dr. Walter Harris, Industrial Toxicologist, Uniroyal, Incorporated, Middlebury, Connecticut; and to his left is Mr. Frank Ryan, Director of Environmental, Health and Safety Affairs for the Rubber Manufacturers Association here in Washington.

The MMA membership is composed of some 180 companies and approximately half of these companies have been affected by the emergency temporary standard and would be more disastrously affected by the proposed standard for vinyl chloride. These companies are involved in every phase of the operations that are under consideration, namely, production of the VC monomer, production of polyvinyl chloride resin, and fabrication of end products from PVC compounds.

While the MMA takes issue with a number of the provisions contained in the proposed standard, we wish to emphasize that we strongly support the principle that there be effective control in the workplace of suspected carcinogens. Although we will articulate certain aspects of the proposed standard, the MMA will also offer constructive alternatives to begin a program of dealing with a very complex problem.

The MMA strongly recommends that there be at least three standards on three applications of one standard for vinyl chloride exposure. The distinction among the three should be as follows:

No. 1, production of vinyl chloride monomer; No. 2, [illegible] vinyl chloride resin; and, 3, processors and fabricators of polyvinyl chloride resin.

Our reason for making this recommendation is that the forms of vinyl chloride that would normally be present in the operations of each of these categories differs greatly from one

operation to another. Furthermore, there is insufficient medical evidence to indicate human health problems at the vinyl chloride level that would be typical in the operations of a PVC processor or fabricator.

We maintain, therefore, that there should be either three standards or three applications of one standard that would establish workpractices proper to and more practical for each of these categories. It is unnecessarily burdensome, impractical, and economically unreasonable to require the same engineering controls, monitoring requirements, recordkeeping requirements, medical surveillance, et cetera, for a PVC fabricator as would be required of a producer of vinyl chloride monomer or PVC resin producer.

The purpose of all standards dealing with toxic materials promulgated by the Occupational Safety and Health Administration, as established by the Williams-Steiger Act of 1970, is "...that no employee will suffer impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

Here, the purpose of a standard for a suspected carcinogen should be to prevent any meaningful or significant [illegible] or exposure -- and that "meaningful or significant" exposure can only be defined as affecting the health and safety of the employee.

The BMA recommends, therefore, that OSHA seriously study the differences in the various workplaces where vinyl chloride is produced, converted into polyvinyl chloride resin, and where the PVC resin is processed. After considering the differences in these different operations, then OSHA should establish workpractices based on a "risk category" approach that will be adequate to protect the employee. The stringency of specific workpractices should be commensurate with the "risk category."

Level of Exposure. Historically, the threshold limit value for vinyl chloride was 500 parts per million based primarily on acute narcotic effects. In 1971, the American Conference of Governmental Industrial Hygienists proposed a tentative value of 200 parts per million. This became effecti e in 1973 as a recognized TLV.

On April the 5th, 1974, the Occupational Safety and Health Administration issued an emergency temporary standard reducing the exposure level to 50 parts per million because OSHA concluded that "there is insufficient evidence at this time to conclude that VC at concentrations of 50 parts per million or below poses a grave danger to humans."

The 50 parts per million was substantiated by the ev - Jones of Professor Maltoni which showed no tumors in animals exposed to VC at a concentration of 50 ppm. The exposure lev: was also substantiated by the evidence of Tockelson, Oyen, and

Rowe, whose data showed that concentrations of 50 ppm failed to induce tumors in rats, hamsters, rabbits, and dogs. However, on May 10, 1974, OSHA published a proposed standard for employee exposure set at no detectable level as determined by sampling and analytical method capable of detecting vinyl chloride at concentrations of 1 part per million plus or minus 50 percent.

In issuing the proposed standard only 35 days after the emergency temporary standard, OSHA concluded that "exposure to VC at 50 ppm may well constitute a serious health hazard to employees."

The rationale indicated by OSHA for proposing a change from 50 ppm to a "no detectable level" has little scientific validity. Because two out of two hundred mice allegedly contracted angiosarcoma of the liver, we fail to see how OSHA can scientifically conclude that exposure to VC at concentrations of 50 ppm can constitute a serious health hazard to humans and thereby propose a "no detectable level."

The PSA also objects to this aspect of the proposed standard which would establish no detectable level of exposure because, as stated in the preamble to the proposed standard, and I quote, "the question of a safe level of exposure for humans cannot be determined at this time, and may continue as a matter for scientific deliberation for many years."

In addition to a lack of medical evidence that a no

detectable level of exposure is necessary, it is also not technologically feasible at this time.

There is a lack of evidence as to the degree of correlation between existing animal studies and human experience data. Thus there is a need for more conclusive studies and analyses before a long-range standard as to specific levels of exposure and workpractices can be established. There is additional ongoing research at the present time and it is absolutely necessary to have significant data in order to make adequate judgments.

Accordingly, while there is has been no significant medical data to justify a change from the current 50 ppm level of exposure, in an effort to arrive at a responsible yet feasible standard, the RMA submits that a standard be adopted with a ceiling level of 40 ppm and a time weighted average of 25 ppm to be in effect for one year, and that this standard be reviewed in light of any and all new data and evidence one yea after its effective date.

Definitions. The term "released" is used in the sco and applies to section and throughout the proposed standard but is never defined. This term is so vague and ambiguous that its interpretation could be misleading. We maintain that the term 'released' should be related to a finite quantity as well as to the concept of "exposure."

Similarly, the definition of "contaminated" is also

Reports. The provisions of paragraph (q)(3) should be amdned so as to require, number one, employee notification when maximum has been exceeded; two, notification within five days; and, three, notification that corrective measures are being taken.

Now, the reporting of "incidents" under (q)(2) is unduly restrictive, and in fact is more restrictive than the present OSHA requirement for reporting fatalities. While fatalities require reporting within 24 hours, there is no requirement for a detailed report within 15 days. For this reason "incident" reporting should be limited to true emergency situations as previously defined, so that the data would be meaningful. Minor excursions about the ceiling or TWA limits will be recorded as part of the regular monitoring program, and such records will be available for inspection.

Your Honor, in conclusion, at this time I would like to ask Dr. Harris to present the concluding remarks.

JUDGE MYATT: Proceed.

DR. HARRIS: Your Honor, it is most interesting to me to take part in this hearing. One of the great problems of the past was that we were unable to bring together all that was known about a large social-scientific-economic problem and to get balanced action. We have been a nation that sometimes lets the pendulum swing from one extreme to the other. Recent examples are DDT, cyclamates, and spray adhesives.

As has been pointed out by others, the PVC industry has grown rapidly during the past 35 years. It started at a time when the field of toxicology was not sufficiently advanced to predict long-term effects of chemicals on man. No one suspected a chronic hazard from vinyl chloride. In the light of present knowledge, it is most regrettable that men were exposed to what we now know were much too high concentrations. We have all learned a great deal since late January. During this hearing labor, management, research, and medical workers have pooled their knowledge and ideas. The challenge to OSHA is to combine all this into a creative rather than a destructive standard.

No prudent manufacturer knowing the vinyl chloride is capable of causing cancer will long take the risk of exposing men to concentrations likely to cause harm. Let us not overlook our competitive system. PVC resin manufacturers will be forced to lower vinyl chloride concentration by competition.

A new criterion has entered the marketplace, and I believe you will see the energies of the large companies turned to solving these problems. Whoever best invests talent and money to build or rebuild plants able to turn out acceptable resins with a low level of vinyl chloride at a profit will stay in business. Others will likely fall by the wayside.

We have a tendency to over-react in this country. It is all or nothing. If we were to drive PVC off the market,

what will take its place? The sheer volume of five billion pounds per year is so large that any substitute will bring about a massive change in our economy. Polyurethanes would involve handling chlorine, phosgene, carbon monoxide, organic diamines, and isocyanates in a tremendous scale. Even cotton causes byssinosis. Let us not jump from the frying pan into the fire.

We believe that the steps already taken have already probably eliminated the health hazard. We urge OSHA to so move as to encourage industry to compete in finding still better long-term solutions. Let us keep alive the dynamic genius which has made America great but not force destructive change.

We believe that an 8-hour time weighted average of 25 parts per million is achievable in the near future. During the next two years much new data will be available. We urge OSHA to keep the regulations as simple as you can, but build in provision for collection of meaningful data for periodic review. If it is necessary to move lower, some will build new plants to meet the new situation. We challenge OSHA to move creatively, not destructively.

Thank you very much.

Thank you very much.

JUDGE MYATT: All right, gentlemen.

Thank you.

Mr. Kuchenbecker?

MR. KUCHENBECKER: Thank you very much for the suggestions and recommendations.

I would like, however, to address a few questions to you.

On page 2 of your testimony you stated that there is insufficient medical evidence to indicate human health problems of vinyl chloride that would be typical in the operations of a PV processor or fabricator.

Do you have any testimony to establish what a safe level would be?

MR. MILLER: What page?

DR. HARRIS: Page 2.

What was your question again?

MR. KUCHENBECKER: Concerning the scope and application.

DR. HARRIS: What do you want?

JUDGE MYATT: He wants the question repeated.

MR. KUCHENBECKER: Do you have any evidence to establish what a safe level would be for human exposure in a PVC or PBC plant?

DR. HARRIS: I don't believe that we have the means

right at the moment to be sure.

I suppose you won't have the means for a number of years.

The only thing we can go on really is the human data and we have the nineteen known cases but they are not really enough unfortunately.

Unfortunately we don't know what those levels were in the early years.

They must have been very high.

I think we are a little bit in the no man's land. We can't get as clear an answer as we would like to it.

MR. KUCHENBECKER: Could you give us any idea of what would be the necessary amount of evidence so that we could form a conclusion on this?

DR. HARRIS: Well, I am sure experts will differ a great deal depending on their expertise.

I really don't suppose that I am really qualified to answer that definitively.

MR. KUCHENBECKER: Is anyone on your panel addressing themselves to that question?

DR. HARRIS: Not definitively, no.

MR. KUCHENBECKER: On page 3 right at the end of the second paragraph you talk about risk categories.

I am a little unclear as to what you mean by that.

Can you explain that for us?

so what we are saying is if the number is what we are recommending, I think it would automatically require the different applications of the standards be made to each of these areas.

MR. KUCHENBECKER: Okay, on 4-5 -- I hope you have the same number -- the last sentence in the top paragraph.

MR. MILLER: Pardon me?

MR. KUCHENBECKER: The last sentence in the top paragraph on page 5 you conclude with the statement that it is not technically feasible at this time as far as achieving really technical levels.

I wonder what basis you have for this statement?

MR. MILLER: In addition to the lack of medical evidence that no detectable level of exposure is necessary.

Is this what you are speaking of, and also not technologically feasible at this time?

MR. KUCHENBECKER: Yes.

MR. WICKHAM: I believe this is based on data which will be submitted as part of Goodyear's information which is to be submitted later, based on monitoring.

MR. KUCHENBECKER: Okay.

The next paragraph you state that we should have a significant data before we make these judgments.

Could you give me any idea of what you mean by this?

MR. MILLER: By significant data?

MR. KUCHENBECKER: Yes.

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DR. HARRIS: I think we will all agree that the objective, that is the ideal thing, of course, would be to have no exposure, none at all.

Unfortunately, in our present state of knowledge, I think it has been brought out clearly by many that we just plain don't know how to achieve that so if you were to try to achieve that you have really only one choice and that is to close down the industry.

This means that the other alternative is that you have to live with some degree of risk.

Now, this is a difficult concept, yet we all do it all the time.

We drive automobiles, we swim, we eat and so on, and I think we just have to come to grips with that problem, even though we would rather say zero, knowing that it can't be done without tremendous changes which may create even greater problems that we have to grow with, some finite risk, some exposure.

This is not very helpful, and I realize it.

MR. KUCHEMEISTER: The last sentence in that second paragraph can make your recommendation as far as a ceiling level of 40 parts per million and a time rate average of 25.

What was the basis for this conclusion on your part?

DR. HARRIS: I think in my own mind the really important figure is the 25 time weighted average.

I think I wasn't present at this particular meeting when this was taken up but I believe the concept here was that we had the faith from experience thus far that if we worked hard enough we would probably be able to achieve it, but it would be very difficult, but they weren't backing away from the difficulty.

I think most of the IVC men are not able to achieve but they are willing to try.

Now, the 40 you could argue with.

Personally, this was a number that was picked. I personally feel that the only meaningful figure really is the time weighted average. Excursions, if you have .pling system that gives you the time weighted average such as the charcoal tube, then excursions within this I don't believe are very meaningful.

I think what they were grappling with here was that they tried to keep it under 40, they will be able to achieve the time weighted average of .5, but I may be putting words in their mouths.

MR. MILLER: I also can add that this is the result of a survey of May 6. We held a meeting here in Washington of the RMA representatives to discuss the temporary emergency standard which is 50 parts per million and lo and behold, during the meeting we got information that we would probably go to zero.

emergency should be that condition that exists over and beyond the maximum level of exposure and we are advocating a 25 TWA and 40 ceiling and anything above that.

MR. KUCHENBECKER: Okay.

Page 9 at the top of the page you state that it should be noted that it is impractical and safe for workers to work with respirators as required by the proposed standard.

How did you reach this conclusion?

MR. MILLER: I think what you have to do is recognize the job classifications and requirements of individuals who operate in PBC.

I think there are some stationary positions where respirators can be worn very effectively.

Whenever you have a condition wherein a multi-story building, for example, where an individual has to maybe go up and down the stairs, work around the reactor and we are talking about, I guess, over a period of an eight-hour day we are talking about several miles of travel and we think this is just completely impractical.

I think this will be pointed out in Goodyear's presentation just how impractical it is.

In many of the buildings this vinyl chloride is being processed.

MR. KUCHENBECKER: Would you object to the use of respirators if the standard were set at such a level that most

PBC manufacturers could get down to it in order to protect their employees, and respirators would seem to be the most logical thing to protect them.

MR. MILLER: You say would I object to respirators in situations where they could not get down to the recommended levels?

MR. KUCHENBECKER: Right.

MR. MILLER: I think there are two answers to that, or at least I would give two.

Number one is if it is practical, and by practical I mean is it feasible for an individual to wear a respirator and yet perform the task without creating an additional hazard. I am talking about the individual who has to climb a multi-story building and do various kinds of things, that is one situation.

On the other hand, the other situation can be an individual who has a stationary position where it could be practical and feasible probably to wear a respirator.

MR. KUCHENBECKER: In the third paragraph on page 9 you state that cartridge type respirators should provide full short-term protection.

Could you give me a ballpark figure there for the use of these cartridge type respirators?

What do you mean by a full short-term use?

MR. WICKHAN: This would be the time required to

exit from an area where vinyl chloride was present about the ceiling or possibly fifteen or twenty minutes or something like that, to shut off leading vessel or correct an emergency situation.

MR. KUCHENBECKER: No more than fifteen minutes?

MR. WICKHAM: Yes, sir.

MR. KUCHENBECKER: On the top of page 10 you give us your suggestions as far as protective clothing.

I take it that you are not including impermeable water resisting clothing.

If so, why is that?

DR. HARRIS: I believe the thing there is we fail to see how it is going to work for the gas unless you really capsulize a person. In other words, if you have coveralls for example, the movement will create suction in and out so that the vapor will get under the clothing and we fail to see that this would really achieve any useful purpose.

We are dealing with a gas, not a liquid, not a solid.

Now, in PBC there is the solid polymer also and it is true it does contain some monomer.

Primarily, I think we are dealing with a vapor that is in the air.

MR. KUCHENBECKER: Let me draw your attention to page 11, maintenance and decontamination.

You state that experience over the years has shown

that may have been visualized here and that is, for instance, that Bendix sequential monitor can be set up so that when you reach a predetermined level, whatever that might be it will sound an alarm.

I believe that is true.

MR. KUCHENBECKER: The section 10 on page 12 deals with polymer handling operations.

There you state the handling conditions shall apply to containers only and the PDC contains one-tenth of a percent or more of residual vinyl chloride.

I am wondering on what basis you have for that statement?

DR. HARRIS: Again, I wasn't at this particular meeting but I don't find any great fault with this.

I think at the time of this meeting many of the companies were really just getting into, I know in our own company we got a lot of reworking of our own on analytical methods which took some time and was quite a little while there that we weren't entirely sure of the levels that we had been reporting on our resin and methods were reworked and changed quite appreciably.

I think at that time they were just beginning to get a feel for what the levels were really in the various polymers at various companies, what they were making and at the same time beginning to get enough feedback as to what levels there

were in fabricating plants.

I believe that the feeling was that if you actually got below, kept it below one thousand parts per million, the levels would be very low in the fabricating plants.

I am not sure that their data -- I am sure it wasn't as good as they would like at that stage -- but I think the principle is sound.

MR. KUCHENBECKER: I have one further question.

MR. WICKHAM: You can visualize a situation where you would have one hundred pounds of resin containing one hundred parts per million and this was put into a work space of one thousand cubic feet and all that monomer were released would result in a concentration of sixty-five parts per million.

This would be with no air change, completely closed system, so that ratio from this one thousand parts per million which we are suggesting you can calculate taking into account air changes what the resultant vinyl chloride concentration in a work place would be or in a contained monomer.

Using this relationship at one hundred parts per million and one hundred pounds of resin if totally released into 1000 cubic feet, would result in sixty-five parts per million in that air.

You can convert this into any concentration you want, taking into account air changes, different amounts of air and resin, different concentrations.

MR. KUCHENBECKER: You have any data on the size of your fabricators in the members of RMA, the size of their plants and the square footage?

MR. RYAN: No, we have not surveyed them to find out the size of the plants, sir.

DR. WHITMAN: I am the one representative on this committee of the fabricators, the only one here who is not a polymerizer and in the RMA I guess we have some forty-four more that are like us, no polymerization and most of them run quite small, too small by far in my opinion, at least to hire biochemists.

A company as large as mine, we can do it.

Our smaller members cannot.

I would like to point out in relation to the question you asked several times earlier, that none of us, what are we doing on engineering procedures to improve the situation.

The fabricator has only two variables really to work with and one is ventilation and the other is the amount of vinyl chloride in the polymer.

And all we have got we can control both of those to some extent and our recommendation here does, indeed, say we would require special labeling on anything over 1,000 parts per million, which would keep these fabricators below the same levels that we are recommending for the polymerizers, twenty-five parts per million.

We have only two things, ventilation and the amount of poly in it.

MR. KUCHENBECKER: I did not catch your name.

Have you considered further enclosures of your fabricating plants?

DR. WHITMAN: Most fabrication operations, it is a manual thing, and the RMA I think will agree every conceiveable kind of vinyl processing.

My own company has almost every conceiveable kind employed.

As somebody mentioned, a man will be handling the webs coming off the calendar. The man at a st ing operation is handling the material.

(Inaudible.)

Or changing wheels in the windup, whatever type (inaudible). Modeling except for the very largest requires manual loading and unloading of the molding machines.

Each one of these things you can't have a man to run it. These are relatively intensive operations.

MR. MILLER: That was Dr. Whitman.

MR. KUCHENBECKER: I have one further question of you, Mr. Miller.

In light of your emphasis on the distinctions of the PBC, would you recommend different exposure levels for various industries?

I think that I have seen it. It is some of the finest work that I have ever seen anywhere and he is thoroughly knowledgeable about the animal end of it and the material he used was unquestionably vinyl chloride, so I could only conclude it is good work and pretty much says what he says it does.

DR. LASSITER: Okay, the reason I asked that last one, you made a statement in your presentation in which you said two out of two hundred mice contacted angiosarcoma of the liver and we fail to see how OSHA can conclude that exposure to vinyl chloride of fifty parts per million can seriously pose a health hazard to humans.

I realize there may be some conjecture about the no detectable level on your part but I am concerned about the serious health hazard to humans.

Is this a correct conclusion?

DR. HARRIS: I guess I shall take that one, too.

I didn't write it but I can't particularly argue with it.

The point is that animal data is helpful. It indicates a possible problem. It doesn't prove anything.

Animals and species of animals can easily vary a thousandfold on some chemistry, that is the amount it takes to produce a toxic effect.

That is not the usual situation.

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Usually, two to fivefold, somewhere in that range, but the fact that a species of animal, especially mice, which can be particularly sensitive; Maltoni, for instance, says the mouse is not the animal to study in this and feels very strongly on that.

Therefore, I don't think it proves anything about humans.

Yet, it is simply a caution flag and that is really all.

The nature of the dose response can be constructive but as far as the actual levels, I don't think they prove anything.

DR. LASSITER: What do you think would need to be done to extrapolate from this type of study to humans knowing that we can't very well expose humans to vinyl chloride and must rely on this type of animal exposure data?

Is this data adequate or not adequate for the purposes we are using it for, that is to set up some types of controls for vinyl chloride?

DR. HARRIS: If you were starting with a totally new research chemical, the situation I am usually confronted with in the company, then we use animal data, of course, as an indicator and we would run into carcinogenicity and it would certainly put up the caution flag and we would think real hard of what sort of tests we could run that were meaningful.

In this case we have a large volume of chemicals which started in an earlier date when we didn't know how to do this sort of thing, so the human exposure took place innocently, not intending to hurt anyone.

I am sure no one intended but it was perfectly obvious as to the possibility there might be a problem.

Since this has happened you already have the human exposure.

We would not deliberately do it that way again, starting from where we are now but since we have the human exposure, that to me is the only place that you are going to get really meaningful data.

I am sure if we had just the animal data and we were starting over the plans would have been engineered quite differently than they are now.

Here, we are at this point in time stuck with multi-billion dollar plants in total. I am just guessing at the figures there and we cannot rapidly change.

DR. LASSITER: Let me be more specific here, and I am sorry if I beat around the bush.

Can you explain to me this phrase in your presentation, that you fail to see how OSHA can scientifically conclude that exposure to vinyl chloride at concentrations of fifty parts per million can pose a serious health hazard to humans.

DR. HARRIS: I think what they were struggling with

when they wrote this, I don't find the exact place quickly here --

DR. LASSITER: It is on page 4.

DR. HARRIS: In the proposed standard where you have concluded previously that fifty parts per million was a reasonable level and then two animals died of industrial bio-tests and the wording sort of indicated that this proved there might be a human problem.

I don't think anything was really changed. All you learned from industrial bio-tests was that mice apparently are a little more sensitive than rats.

It did not change the toxicity. It did not prove anything about humans, just one more caution flag.

DR. LASSITER: One more and this is on the animal species.

I think there are three now.

The only other question I have and I only bring this up because you mention it in your answer, and it is an area that we need information on and assistance on, and that is in the area of risk.

I agree with what you said that we, indeed, so assume risk about many everyday things.

Do you have any type of guidance you can give to OSHA and the Assistant Secretary in reaching a decision based on the fact that there may be some risks that will have to be

assumed?

DR. HARRIS: Well, I would go along with the numbers that are given here and are given by SPI as being about as good as you can come up with as a compromise between what you would like to do and what you possibly can do in the foreseeable future, but you know just what the element of risk is, and I personally think it is exceedingly small, but I couldn't prove.

I could be wrong.

DR. LASSITER: Thank you.

JUDGE MYATT: Any other questions?

All right, questions from the floor.

MR. BOGESE: My name is Paul Bogese, Virginia Plastics.

You keep talking about clothing to protect workers.

Has there been any data to prove that vapor goes through the skin, some other part of the body, other than breathing?

I keep wondering why put it in there?

DR. HARRIS: I believe there was one animal, one monkey exposed to vinyl chloride through the skin.

MR. MILLER: Two monkeys.

DR. HARRIS: I really don't know too well the data except that I believe the monkey was, you might say, encapsulated except for its head.

The body was exposed to the vapors and the breath was checked for vinyl chloride and they found vapors in the breath which indicated it had gone through the body somewhere.

MR. BOGESE: Okay.

I was wondering why they got around to that.

DR. HARRIS: I don't know at all quantatively what it was.

I am sure it wasn't scientific enough.

MR. BOGESE: Thank you.

JUDGE MYATT: Any other questions?

MR. BECKER: I am Bill Becker of B. F. Goodrich.

Mr. Miller, I have just a couple of questions to firm up my understanding.

You were talking about emergency before, I think, and we are trying to define emergency and I believe in answer to one of the questions asked you talked about an emergency level being a level or any level over the accepted level of say forty which is being proposed here.

Is that what you meant, that that was the definition of an emergency level?

DR. HARRIS: I don't really believe that is what you mean, Bill, or what they meant when they wrote this.

MR. BECKER: I was a little confused by that.

DR. HARRIS: I think they were thinking of rather massive spills or leaks at a monomer plant where you could

get a thousand parts per million; you could get explosive concentrations and this would be a real acute hazard that has to be taken care of.

MR. BECKER: Yes.

And not any exposure over forty, say forty-five, would be an emergency?

DR. HARRIS: I don't believe so.

MR. BECKER: You were asked something about the acceptability of the use of respirators and you turned your attention, I believe, Mr. Miller, to a question of location, primarily a situation that if someone had to move up and down it might be different than if one had to stand in place.

Are you also, however, indicating the acceptability has something to do with time?

MR. MILLER: Yes.

MR. BECKER: Even if someone were standing in one place, I assume that if one had to wear one all the time you would consider that acceptable or unacceptable?

MR. MILLER: If we are talking about an eight-hour shift it might mean this might not be acceptable.

MR. BECKER: Thank you, Mr. Miller.

MR. CONNOLLY: Dr. Harris, just one short question.

Based on the studies that you have seen and what you have done in this area, can you discern or predict any appreciable difference in the effects on an individual who is

exposed to polyvinyl chloride at twenty-five parts per million versus being exposed to fifteen or twenty parts per million or would the effects be the same in any case?

DR. HARRIS: I really believe that if you look at the nature of the exposure curve in Maltoni's work and other carcinogenic studies, the difference between ten and fifty isn't very much, that is, it really is at times the concentration that becomes important.

A single excursion is pretty much meaningless.

MR. CONNOLLY: Assume the constant exposure is over an appreciable period of time, and if there is no difference between twenty-five and ten, do you agree with Dow and Air Producers doctors?

Do you agree with them?

DR. HARRIS: I would tend to. It would be so small it really wouldn't be very significant.

MR. CONNOLLY: Thank you very much.

JUDGE MYATT: Any further questions from the floor?

(No response.)

JUDGE MYATT: All right.

Thank you.

We are going to adjourn for the evening. We will resume these hearings at nine o'clock tomorrow morning.

I might also apprise you of the fact that depending upon our rate of progress, we will probably go late tomorrow

United States Department of Labor
Occupational Safety and Health Administration
PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE
Washington, D. C.
July 8, 1974
Pages 1107 thru 1315

E R R A T A S H E E T

PAGE NO.	LINE NO.	
1108-A	7	Add Exhibit No. 31 - Marked at Page 1315
1111	19	Change "PBC" to "PVC"
1115	8	Change "monimer" to "monomer"
1116	4	Change "handing" to "handling"
1117	16	Change "yeats" to "years"
1118	4	Change "polymizers" to "polymerizers"
1118	5	Change first "and" to "any"
1119	19	Change "tooms" to "rooms"
1122	11	Change"to" to "through"
1123	24	Delete "improvement"
1123	25	Change "the to "our"
1126	22	Change "belowe" to "below"
1127	7	Change "fill" to "full"
1129	19	After the word "attached" add "When he concludes his testimony, I will make a summary statement."
1135	23	Add the word "antigen" between the words "liver-specific studies"
1138	24	After the word "question" add "I believe we have a 10-year retention plan, although now"

PAGE NO.	LINE NO.	
1139	13	Change "problem" to "probe"
1140	11	Change "here a" to "very"
1140	23	Change dreived" to "arrived at"
1141	23	Change "voracity" to "porosity"
1142	14	Change "polymerization" to "olymerizer"
1142	15	Change "recognized" to "mechanized"
1143	4	Change "peak" to "high"
1143	5	Add "quick" between the words "rather" and "purging"
1144	10	Change "sypply" to "supply"
1145	13	Add "As it is opened" after the word "opening"
1145	15	Change "The limit of its availability" to "The limit of its ability to remove"
1146	12	Add after the words "vacuum pumps, valve systems", "condensers, pump packing,"
1146	19	Add the words "with closure" after "man-hole"
1147	2	Change "has" to "have"
1147	3	Change "Defamation" to "defamation"
1147	4	Add "seal" after "nozzle"
1147	12	Delete the word "that"
1148	4	Add the word "level" between the words "magnetic indicators"
1148	9	Delete the word "the"
1149	25	Add "fewer potential leak sources" after the words "87 percent"
1150	12	Add "most of" and "get the"

PAGE NO.	LINE NO.	
1150	13	Change "charge" to "charged"; change "going" to "blown"; add "attention" after the word "manuel"
1150	17	Change "slurring" to "slurrying"
1150	22	Change "monomer" to "vinyl"
1150	23	Change "on" to "in"
1150	23	Change "surface" to "slurry"
1153	21	Add after the word "get", "there"
1154	11	Add after "require" the words "the use of"
1154	11	Add "at" after the word "protection"
1154	12	Add "in order to" before the word "stay"
1154	14	Change "modern" to "Monomer"
1154	19	After "data," add "that we gathered in two months"
1156	12	Change "it would be" to "vinyl chloride vapor; yes."
1157	10	After "study" add"that is envisaged here"
1158	11	Change "series" to "theories"
1159	14	Change "abnormal" to "typical"
1159	18	After the word "have" add "significant"
1159	19	Change "death" to "test"
1160	1	Add after the word "variance" the words "Strawberry City, Kentucky, 17%"
1160	11	After the word "two" add "standard"
1160	15	After the word "of" add "young"
1161	17	Add after the word "no" the word "feeling"

PAGE NO.	LINE NO.	
1161	18	Delete comma after "but"
1163	4	Change "DDO" to "do"
1163	1	Change "metabolic" to "metabolics"
1163	10	After "the" add "Kupper Cell"
1163	14,15	Delete " DR. MOORE"
1163	15	Delete "MR. KLINE:"
1165	12	Change "health research" to "Health Research"
1165	15	Change "ADL" to "APL"
1169	2	After the word "prompted" add the words "the liver function testing of 271 BF Goodrich markers"
1169	4	After "Dr. Creech's" add "impression"
1169	5	Add "the rest of" after the words "workers than in"
1169	8	Change "disease function" to "dysfunction"
1169	11	Change "in" to "since"
1169	14	Change "disease function" to"dysfunction"
1169	19	Change "functioning" to "dysfunctioning"
1170	4	Add after the word "time" the words "in developing"
1170	4	Add after the word "protocol" the word "for"
1170	10	Add "EDC" after the word "practicing"
1170	11	Change "get" to 'am not"
1170	12	Add the word"however"
1170	17	After the word "not" add the words "of Italian experiments showing"
1170	18	Add a comma after "73" and change "But" to "but"

PAGE NO.	LINE NO.	
1170	23	Add the words "Italian Data?" to end of sentence
1171	2	Strike the word "of"
1171	18	Change"OBA"to "OVA"
1171	21	Change "OBA" to OVA"
1180	21	Change "ventillation" to "ventilation"
1182	4	After the word "indices" add "% of"
1183	4	Change "medium" to "median"
1183	8	Add the words "sort of cancer case" after the word "any"
1183	12	Add the words "high to me."
1183	25	After the words "question to" add "Dr. Johnson"
1184	24	Change "air products" to "Air Products"
1184	25	Change "chemicals" to Chemicals"
1189	7	Change "scrap" to "gap"
1189	20	Delete "for" and add "on behalf of"
1189	21	After "everybody"add "I"
1189 & 1190		Reverse these pages. 1190 should be 1189 and 1189 should be 1190.
1190	19	Delete "He raised the good stuff"
1191	10	Change "Manger" to "Manager"
1195	23	Change "Tinyl" to "vinyl"
1197	7	Change "conerned" to "concerned"
1199	1,2,11,15	Change "Mr. Kuchenbecker" to"Mr. Klein"
1199	11	Change "resing" to "resin"

PAGE NO.	LINE NO.	
1200	12	Change "MR. KUCHENBECKER:" to "MR.KLEIN:"
1200	21	Change "funtion" to "function"
1200	24	Change "interest" to "limit"
1201	15	Add ";" after "most"
1201	15	Add "you" after "are"
1204	17	Change "backup" to "BAQ"
1205	18	Delete "was a consideration" and add "consists"
1205	19	Change "an" to "then"
1205	19	Change "analysis" to "analyzed"
1205	20	Change "bo contrast" to "by Gas Chromatography"
1206	9	Change "erring" to "eering"
1206	15	Delete "out" and add "our older"
1206	15	Delete "and" and add "that"
1206	22	Change "Jons" to"Johns"
1207	2	Delete "not"
1207	6	Delete "and"
1207	13	Change "beloc" to "below"
1209	1	Delete "If it pleases" and add "from"
1209	1	Add "standpoint" after "administrative"
1209	4	Change "PVE" to "PVC"
1210	7	Change "MR. SALES" to "MR. SELLS"
1210	10	Change "MR. SALES" to "MR. SELLS"
1210	20,21	Should read: "have, to use something else, we have no reason - - -"

PAGE NO.	LINE NO.	
1211	11	Change "polyethylenes" to "polyolephins"
1211	12	Change "extrusion" to " substitution"
1211	12	Change "polyethylene" to "polyolephin"
1211	16	Change "polyethylenes" to "polyolephins"
1211	22	Change "Palmer policy" to "VC monitoring"
1212	14	Change "MR. RIDES:" to "MR. REITZ:"
1212	17	Delete "This has subsequently been attributed to the material," and insert "Subsequently to the typing of this material"
1212	18	Change "We've" to "we've"
1213	17	Delete "plus" and add "less than"
1214	22	Delete "and" and add "..."
1215	11	Change "that" to "to"
1219	5	Change "acrylonitrites" to "acrylosteolysis"
1221	2	Change "it" to "a"
1221	18	Delete "an" and add "point of"
1222	17	Change "goes" to "stood"
1223	18	Change "Jackson" to "Tucson"
1223	22	Delete "it"
1224	5	Change "where" to "what"
1224	6	After the words "of monitoring" add the words "is why"
1224	11	Change "and" to "or"
1224	11	Before the words "solely attributable" add the word "it"
1224	21	Change "technical" to "detectable"
1224	22	Change "competence" to "confidence"

PAGE NO.	LINE NO.	
1224	25	Change "technical" to " detectable"
1225	2	Change "say" to "see"
1225	2	After the words "if you have a problem" Delete the word "if" and add the words "and after"
1225	12	Enquote the words "detectable levels" so they read ""detectable levels""
1225	23	After the words "permissible level," add "and"
1226	4	Should read " Doesn't that set ranges? This seems to me to give a "
1226	10	Change "technical" to "detectable"
1227	17	Change "participation" to "prop "
1227	24	Change "solids" to "resins"
1229	20	Change "CDIH" to "ACGH"
1230	1	Change "transplocebe-transcendially" to "transplauntally"
1235	17	Change "polyethylene" to "polyolephins"
1236	10	Change "ther" to "other"
1236	22	Change "technical" to "detectable"
1237	20	Change "Cather" to "Carter"
1237	21	Change "26-A" to "28-A"
1238	7	Change "four" to "five"
1238	8	Add "28-A" after the word "exhibits"
1290	24	Change "PVC" to "VC"
1290	24	Change "PBC" to "PVC"
1292	16	Change "PBC" to "PVC"

PAGESNO.	LINE NO.	
1295	7	Change "PBC" to "PVC"
1299	1	Change""PBC" to "PVC"
1300	19	Change "PBC" to "PVC"
1302	9	Change "PBC" to "PVC"
1304	10	Change "fire" to "hire"
1305	24	Change "PBC" to "PVC"

WHEREVER THE FOLLOWING NAMES APPEAR CHANGE THEM;

from "MR. COTTE" to "MR. COTTINE"

from "MR. HECHMAN" to "MR. HECKMAN"

from "MR. KLINE" to "MR. KLEIN"

from "MR. RIDES" to "MR. REITZ"

from "MR. RITES" to "MR. REITZ"

from "MR. SALES" to "MR. SELIS"

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American Chemical Society

DEPARTMENT OF CHEMISTRY
AND PUBLIC AFFAIRS

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4600

July 8, 1974
120-424-74

The Honorable Gordon J. Myatt
Administrative Law Judge
Occupational Safety and Health Administration
U. S. Department of Labor
Washington, D. C. 20210

Dear Judge Myatt:

We are enclosing, as requested, three copies of the official policy statement of the American Chemical Society on the Occupational Safety and Health Administration's proposed Vinyl Chloride Occupational Exposure Standard. Unfortunately, Dr. Robert W. Cairns is not able to be here today, so I will present the statement.

The American Chemical Society appreciates the opportunity to respond to the request for comments and recommendations on the proposed Standard.

Respectfully yours,

Stephen T. Quigley

Stephen T. Quigley

Enclosures (3)

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July 8, 1974

In the absence of Dr. Robert W. Cairns, the statement will be presented by Dr. Stephen T. Quigley of the Department of Chemistry and Public Affairs.

STATEMENT

of

DR. ROBERT W. CAIRNS

on behalf of the

AMERICAN CHEMICAL SOCIETY

to the

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

UNITED STATES DEPARTMENT OF LABOR

on the

PROPOSED VINYL CHLORIDE OCCUPATIONAL EXPOSURE STANDARD

[29 CFR Part 1910.93q]

July 8, 1974

Your Honor:

My name is Robert W. Cairns. I am the Executive Director of the American Chemical Society and I appear before you with the authorization of the Society's Board of Directors to present this statement. Accompanying me today are Mr. Howard K. Fawcett, Chairman of the Committee on Chemical Safety of the Society, and Dr. Stephen T. Quigley of the Society's Department of Chemistry and Public Affairs.

We appreciate the opportunity to respond to the request for comments and recommendations regarding the Occupational Safety and Health Administration's Proposed Vinyl Chloride Occupational Exposure Standard. It is appropriate that the American Chemical Society present this statement since it has a National Charter which imposes obligations on the Society to provide assistance to the government in matters of national concern related to the Society's areas of competence and also to work for the advancement, in the broadest and most liberal manner, of chemistry,

"thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

Founded in 1876, the American Chemical Society was chartered as a non-profit, scientific and educational organization by an act of Congress which was signed into law on August 25, 1937. Current membership in the Society is about 110,000 individual chemists and chemical engineers. The Society has no corporate memberships. The membership reflects a broad spectrum of engagement in academic, governmental, and industrial professional pursuits. About 60% of our members are employed by industry, about 25% by academic institutions, and 15% by government and nonprofit institutions.

The Society's Committee on Chemical Safety, whose membership includes persons with recognized expertise in chemical safety matters from universities, industry, labor, government, and the medical field, has long been concerned with the physical safety and well-being of practicing chemists, engineers, and persons working with hazardous and potentially hazardous materials. In its consideration of the proposed vinyl chloride standard, the Committee on Chemical Safety has also consulted with scientific experts outside the membership of the Society to broaden the Society's perspective on this issue.

The recommendations of the Committee on Chemical Safety have been reviewed by two additional Society Committees -- the Committee on Environmental Improvement and the Committee on Chemistry and Public Affairs -- before being reviewed and approved by the ACS Board of Directors. We believe this statement of the American Chemical Society represents a consensus of recognized experts within the chemical science community.

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Chemicals, in a wide variety of forms, constitute the basis for all life. Approximately 4.5 million chemicals have been isolated and identified. Thousands of these chemicals are safely manufactured, transported and used in large quantities. Thousands more are used in smaller quantities for very limited and specific purposes over a wide spectrum of human endeavors, frequently by the public. Often a chemical will possess one or more properties which present a hazard to human health or safety, such as explosiveness, corrosivity, toxicity, flammability, or carcinogenicity. However, carcinogenicity presents special problems in establishing controls because the minimum amount required to induce effects in humans is generally not known, and there frequently is a long induction period between exposure and effect.

The American Chemical Society has carefully reviewed the most recent information [1-8] on the subject of vinyl chloride and polyvinyl chloride which contains variable amounts of unreacted vinyl chloride in occupational exposures and the suspected relationship of vinyl chloride to angiosarcomas in humans. In the general population, angiosarcoma is a rare carcinogenic lesion. Vinyl chloride has been found to induce angiosarcomas of the liver in mice at exposure levels as low as 50 p.p.m. within a period of six months and as low as 250 p.p.m. in rats within a period of two years. This information on experimental animals, when considered in relation to the discovery of the same rare angiosarcomas of the liver in humans who had been exposed to vinyl chloride, probably at high levels over a period of years, strongly suggests a cause and effect relationship between vinyl chloride exposure and the appearance of the angiosarcomas in humans. There also appear to be indications that vinyl chloride is a carcinogen for sites other than liver, [3,6,7] but epidemiological studies are necessary to confirm these preliminary findings.

What remains in question is the actual minimum level of exposure to vinyl chloride which may induce angiosarcomas in humans. While some chemical carcinogens

have indeed been found to have an apparent threshold value, the Society recognizes that there are no scientific data currently available to set conclusively a threshold limit for safe exposure of humans to vinyl chloride. The Society recommends continuing experimentation to define a threshold value for carcinogenicity of vinyl chloride, both for sustained and for intermittent exposure, and periodic review of the standard in light of new data that indicates or defines this value. The Society recommends similar investigations for any possible carcinogenic effects from associated contaminants in vinyl chloride. Structural analogs to vinyl chloride should be investigated for carcinogenic effects as well.

In the absence of data establishing a safe level of exposure to vinyl chloride and in the interests of public health and welfare, the Society endorses the proposed standard for the level of employee exposure. 1/ However, the Society believes that the standard for employee exposure would be clearer if set at a minimum practical level capable of detection by a recommended method rather than at no detectable level. A probable method of choice for detecting and measuring vinyl chloride in occupational exposures is gas chromatographic analysis of vinyl chloride collected from air samples by adsorption on activated carbon. Although other relatively inexpensive and simple methods of detection already exist that are capable of sensing low levels of vinyl chloride, the Society encourages continuing research to develop improved analytical methods for reliably identifying and measuring the presence of vinyl chloride.

The American Chemical Society is aware that some steps are being taken by industry to reduce the risk of exposure to vinyl chloride, and the Society recommends that a reasonable period of time be given employers to allow for the detailed engineering design and development of equipment necessary for full compliance with the standard. The control methods outlined in the standard appear to the Society to be reasonable, but a desirable additional precaution should be for workers to be required to wear air-supplied suits fabricated from materials that are in effect

impervious to vinyl chloride for exposures in excess of the standard. A schedule should be developed that is determined by the specific needs for protective equipment against exposure at various levels to vinyl chloride and polyvinyl chloride which contains variable amounts of unreacted vinyl chloride. Development of appropriate maintenance and decontamination procedures for such equipment will be necessary.

The American Chemical Society is concerned that increased reliance on ventilation methods as dealt with in sections (1)(6) and (n) of the standard does not ameliorate the problem of the potential hazard to the general public from ambient levels of vinyl chloride, although a local exhaust ventilation system to reduce the concentration of vinyl chloride may help provide safeguards for an employee in the immediate vicinity. While a preliminary survey by the Environmental Protection Agency [8/] has indicated the presence of ambient levels of vinyl chloride under present plant operating conditions that are in excess of the proposed exposure level in the standard, most ambient levels of vinyl chloride appear generally to be below the level in the standard. However, the Society recommends continuous monitoring in the vicinity of such plants to ensure maintenance of low ambient levels of vinyl chloride. In the event that low ambient levels are not maintained, adsorption or scrubbing techniques may be necessary to reduce the level of vinyl chloride.

The Society wishes to emphasize that adequate labeling must be maintained at all times to achieve the objectives of the provision that transporters, handlers, disposers, and others exposed incidentally or occasionally, such as firemen, be properly informed of the potential hazards and be adequately trained in the safety precautions to be observed. A clear and comprehensive definition of the word "vessel" in this context should be included in section (b) of the standard.

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The Society has long encouraged and supported the rapid and wide dissemination of information on the potential hazards of chemicals. To promote the dissemination of information on chemical carcinogens, including vinyl chloride, the ACS Committee on Chemical Safety has scheduled a symposium on the topic for the ACS National Meeting in Atlantic City, New Jersey in September 1974.

In summary, the American Chemical Society concludes that even the potential threat of exposure to vinyl chloride justifies the adoption of the proposed standard for occupational exposure. The Society believes that the control methods outlined in the standard are feasible, but urges that provision be included for a reasonable period to comply with the standard. The Society offers these remarks on the proposed standard of the Occupational Safety and Health Administration in a spirit of cooperation to achieve the minimum practical risks from vinyl chloride exposure. It is the Society's hope that the proposed standard for vinyl chloride exposure be adopted and that it be periodically reviewed as new data become available.

Attachment: References

References:

1. Federal Register, 39 (92), 16896-16900 (1974).

2. C. Maltoni, et al., Record of a fact-finding hearing on possible hazards involved with the manufacture and use of vinyl chloride, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, D.C. (February 15, 1974).

3. P. L. Viola, "Cancerogenic Effect of Vinyl Chloride," Abstr. 10th International Cancer Congress, Houston, Texas (May 22-29, 1970), p.20; P. L. Viola, A. Bigotti, A. Caputo, "Oncongenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride," Cancer Research, 31, 516-522 (1971).

4. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois, under contract to the Manufacturing Chemists Association, Washington, D.C. Press Release, MCA-3839 (April 15, 1974).

5. Tabershaw/Cooper Associates, Inc., Berkeley, California, under contract to the Manufacturing Chemists Association, "Epidemiological Study of Vinyl Chloride Workers," Final Report (May 3, 1974).

6. Office of the Scientific Coordinator for Environmental Carcinogenesis, Division of Cancer Cure and Prevention, National Cancer Institute, National Institutes of Health, U.S. Department of Health, Education and Welfare, "Vinyl Chloride Exposure and Neoplastic and Non-Neoplastic Disease," transcript of the 9th meeting of the Interagency Collaborative Group on Environmental Carcinogenesis (April 17, 1974).

7. New York Academy of Sciences symposium sponsored by the American Cancer Society, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health, and the Society for Occupational and Environmental Health, "Working Group Toxicity of Vinyl Chloride - Polyvinyl Chloride," Delmonico Hotel, New York, New York (May 10-11, 1974).

8. A survey of approximately one-third of vinyl chloride and polyvinyl chloride plants indicates ambient levels of vinyl chloride, and the Environmental Protection Agency has requested data on losses into the air to consider whether to issue an emission standard. EPA Press Release, No. R-471 (May 31, 1974) and EPA Press Release, No. R-481 (June 11, 1974).

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MR. KUCHENBECKER: Let me direct your attention to the second paragraph on page 4. The second sentence, you state: "However, the Society believes that the standard for employee exposure would be clearer if set at a minimum practical level capable of detection by the recommended method rather than at no detectable level."

Do you have any set level that you would suggest for this?

DR. QUIGLEY: No, sir.

MR. KUCHENBECKER: All right. The bottom paragraph on page 4, you state that you recommend a reasonable period of time to be given to employers to ultimately fulfill engineering design and necessary equipment.

Could you give us any suggestions that you feel would be proper for a reasonable period of time?

DR. QUIGLEY: No, sir. This, you have had considerable testimony from the practitioners in the field about the difficulties involved and while the Society endorses the standard as proposed, we recognize the technical and practical difficulties in achieving this and in working environment and all we are recommending is that the Labor Department establish a practical timeframe for reaching the industry, to reach this, and we don't have any specific recommendation.

MR. FAWCETT: I think the thing there, that Dr. Quigley is referring to, is that some things can be done very

rapidly.

On the other hand, if you have the scrubbers, adsorbers, ventilators, other large equipment that has an 18-month or two year delivery time, it's obviously not practical.

The alternative would be to shut down everything. That may be the alternative that you would have to have if you want to enforce the standard but this should be on accredation period depending on what can be done in reasonable time.

That is what the word reasonable in this case does. It is reasonable to the sense that some things can be done right away and other things take a little longer.

MR. KUCHENBERGER: Thank you.

On page 5, your second paragraph there, the second to the last sentence, you are speaking of monitoring; you recommend a continuous monitoring in the vicinity of such plants in low ambience levels of vinyl chloride.

Let us be a little more specific here.

Do you recommend area monitoring backed up with personnel monitoring? Any specifics that you have in mind? You mentioned continuous monitoring.

DR. QUIGLEY: Well, I think that if you refer to the EPA report on the recent report on the presence of the levels of vinyl chloride in the vicinity of operating plants,

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with the labeling proposed in the presently proposed standards?

DR. QUIGLEY: Yes, sir, I think that is fair.

MR. FAWCETT: Especially if the word vessel is a little more clearly defined.

The word vessel means many things to many people. Frankly it is a word that is not very clear in context of exactly what you mean by vessel.

Is this a vessel? It is a vessel for water, obviously. It wouldn't be a vessel for vinyl chloride because vinyl chloride is a gas under normal conditions.

I think the word vessel, particularly where you are talking about labeling vessels, there needs to be better definition.

MR. KUCHENBERGER: I have one further question. On page 6, the second paragraph, you conclude the statement that: The Society pleads that the control methods outlined in the standard are feasible -- "

Was your presentation today based at all on any considerations of economic or technical feasibility?

DR. QUIGLEY: Based on the control methods that are technically feasible, yes.

Now, if you consider the adaptation of technically feasible control in all circumstances, the Society has not done complete economic analysis, but no, sir.

MR. KUCHENBERGER: Thank you.

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MR. HECKMAN: And did the deliberations include any study of technical or economic feasibility with respect to the standard?

DR. QUIGLEY: If you would qualify the word study.

See, when you talk about study, it denotes something relatively long-range and I hope that you understand that these committee deliberations were conducted in the last three months.

And what we are, what the committees did, of course, was to draw on the resources on the individuals and institutions from which they came.

So the knowledge that was brought to the deliberations, reflects of course knowledge of studies that have been conducted, a number of studies.

A direct answer to your question, did the committees conduct any studies other than deliberations during the committee meetings -- no.

MR. HECKMAN: And you haven't conducted any surveys or interviews or plant walk-throughs or anything of that type as a committee with respect to the technical feasibility of achieving the standard?

DR. QUIGLEY: No, sir.

MR. HECKMAN: The Society from time to time funds research, does it not?

DR. QUIGLEY: Yes and no.

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Society --

DR. QUIGLEY: I presume a transcript of these hearings will be made available?

MR. HECKMAN: It would be made available and it might have posthearing comments because I think the opinion of the American Chemical Society might be interesting.

Does the Society have any data to the best of your knowledge, on either animal toxicology, human epidemiology or any other phase of the safety aspects of this matter that have not been published and is otherwise well known, to the best of your knowledge?

DR. QUIGLEY: When you talk about society, are you talking about the institution or are you talking about the membership society?

I would assume that among the membership society there is a great wealth of knowledge in this area.

The institutional sources of information would be of course the publications.

MR. HECKMAN: Do you have any additional data on animal toxicology or human experience that you can submit for this record on and in your offices or can you obtain any?

DR. QUIGLEY: To answer your question in two ways: First, no, we do not have information available in our office at this time.

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I am sure if a study were conducted more information could be made available but as I indicated earlier, this kind of study and an organization such as ours would take longer to organize and complete than the record for this hearing would allow.

MR. HECKMAN: I hope you understand that my questions have to be framed the way they are because you are supporting the standard.

DR. QUIGLEY: Yes, sir.

MR. HECKMAN: And we need to have a basis on which to understand your basis for supporting the standard.

DR. QUIGLEY: Right, yes, sir.

MR. HECKMAN: If I understand it correctly, you have no additional data on technical or economic feasibility or toxicology, human or animal, that has not been presented here to the best of your knowledge?

DR. QUIGLEY: At this time, that is right, yes, sir.

MR. FAWCETT: I might just add, Dr. Quigley, this testimony as given by Dr. Quigley and myself today, will be published in next week's issue of Technical and Engineering news which is the publication that goes to 110,000 members of the American Chemical Society.

I can assure you within the next two weeks, Dr. Quigley's mail and my mail will go up two degrees of magnitude than what it is and if there is any little juicy

mx32

Dr. Quigley, in the colloquy, there may have been, I forgotten which of you gentlemen, but in the colloquy about threshold levels with Mr. Heckman and Mr. Kline with respect to some chemical carcinogen levels, you indicated you would check into which carcinogens had thresholds and what those thresholds were.

I wonder if you recall what the order of magnitude of those thresholds are to the extent you can recall.

Were we talking about five ppm's or 10 or 50 or what?

DR. QUIGLEY: Sir, I am sorry I can't give you a specific figure.

MR. TOPOL: Could your colleague give any recollection?

DR. QUIGLEY: I am sorry, I guess when I don't have data, I say I don't know. That is the situation that we have instantaneously.

MR. TOPOL: In connection with the angiosarcoma cases, the human cases in the United States which there are 13 cases at American plants, we have had testimony to the effect that seven cases were the single plants, three were in the second plant, two were in one and the one was in another.

We have also had testimony that there are eight plants 20 years and older in the United States and four plants had no cases and again, I recall the fact that one plant had seven cases.

What explanation would you offer for this fact occurring?

DR. QUIGLEY: I would have no explanation.

MR. TOPOL: Is it one possible explanation --

MR. FAWCETT: May I take a crack at this one? I realize I shouldn't stick my neck out, but I really feel that I should.

In the first place, there is tremendous variations in human beings just as there is tremendous variation in laboratory animals.

And to say there is so many cases in one plant and 500 miles away there is something else in another plant, those people live different lives.

They are exposed to all sorts of different things.

Some people even do nasty things like smoking cigarettes and drink whiskey, all of which might have some bearing on this carcenogenic exposure.

Many plants are built in different ways. They were built by reputable companies for different purposes. So there could be tremendous variations.

I wouldn't lean too strongly on the limited, limited -- I am sorry that any occurred, don't misunderstand the statement but I wouldn't spend too much time on trying to correlate numbers because I don't think the numbers have any significance either way to say zero here and ten here.

These numbers were accumulated as a result of a sudden new interest that developed.

I have a feeling many factors were involved and that, you know, I think anybody that looks into the biology of the human system can put their fingers on many possible variables.

MR. TOPOL: Okay. Following that up if we can, is it one possible explanation the fact that exposure levels in the plants which had employee cases with higher than exposure levels and the other plants and that the higher exposure levels were the cause?

MR. FAWCETT: Undoubtedly it could be a factor, yes.

MR. TOPOL: And then if you sort of pursue this, wouldn't it be possible that if we knew the exposure levels in the plant in which there were no cases, we could reach the conclusion that these levels of exposure were safe levels, that is, they were below the threshold that you talked about?

MR. FAWCETT: Well, you are now extending your logic in an illogical manner. Because when one applies that kind of logic to the human systems, one is in trouble, particularly when the induction period is five, ten, 15, 20 years.

There is too many variables in a lifetime. I have had some pretty severe traumas and severe exposures to an awful lot of chemicals and an awful lot of things in a lifetime.

I am curious to see my own death certificate because I am curious to see what I died of, because it could be a

ek35

number of things, all of which could be perfectly justified but I don't know.

I think to follow the kind of logic that your mind is taking too at the moment, is going to lead you to erroneous conclusions.

MR. TOPOL: Well, my question to you is, once you postulate the fact there might be threshold levels, say, threshold for this chemical exposure, isn't it possible that the reason that there were no cases at a number of plants is because levels did not exceed that threshold?

I mean, I realize that we can't say for certain.

MR. FAWCETT: That is one possibility, yes.

MR. TOPOL: Let me follow that one step further and tell you that we have had -- let me ask you, we have had testimony from the Dow people who did a complete survey on all their employees and concluded that they found increased malignancies among employees exposed for long periods above 200 ppm and no increased malignancy, indeed decreased malignancies for employees exposed below 200 ppm.

How would that relate to what we are talking about? Wouldn't that tend to confirm the threshold thing that you and I have been discussing?

MR. FAWCETT: Yes, 20 years from now chances are you can come to such conclusion.

It is the induction period that makes it so

Is that Dr. Quigley, accurate?

MR. FAWCETT: Chemical analogs.

MR. TOPOL: Could you explain in detail why it is you want to test, why it is you want to test the chemical analogs, what the point of that is?

DR. QUIGLEY: Well, I think that when you are concerned about the hazardous effect of any chemical that when you consider the analogs of any structure that is hazardous, you want to find out what possible hazards there are in the analogs that might be similar and so it is a natural tendency for research chemists of investigate the analogs of any compound.

MR. TOPOL: Do you also endorse testing the other compounds to which employees of vinyl chloride operations might have been exposed at the same time that they were exposed to vinyl chloride, is that implicit in your statement?

I am asking it. I didn't understand it.

DR. QUIGLEY: Right, the statement says specifically the Society recommends similar investigations for any possible carcenogenic effect from associated contaminants for vinyl chloride and then to extend that, I think it would be a fair inference that we would and have historically been in favor of investigating the safety aspect of all chemicals and all compounds and all materials that people working in chemical plants have to deal with.

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MR. TOPOL: Does this relate back to the earlier point we had in the colloquy that perhaps the fact that employees exposed to vinyl chloride were also exposed to a second chemical that it is this combination of chemicals, the so-called synogistic effect that produces the angiosarcoma?

Would that be the point of research to see if that occurs?

DR. QUIGLEY: I think it is a supposition and I don't think we are qualified to answer that at this particular point in time.

MR. TOPOL: That is the subject that needs research, I gather, from your testimony?

DR. QUIGLEY: I think so, yes.

MR. TOPOL: What final area briefly, please.

Did I understand your testimony to be that you have concluded that the proposed, that the level in the proposed standard could be feasibly attained in current facilities if a sufficient time were provided for engineering changes, is that the essence of your testimony?

DR. QUIGLEY: Yes, sir.

MR. TOPOL: Okay. What do you base your conclusion on that the proposed standard, even with time, with assuming now unlimited time if you would, assuming unlimited time, what is the basis for your conclusion that the level of the proposed standard can be technically attained?

DR. QUIGLEY: Well, the basis is that technologically feasible to detect the levels of the proposed standard level.

Now specifically, I would have to repeat the written testimony that, the conclusion of the Society is that even the potential threat of exposure to vinyl chloride justifies the adoption of the proposed standards for occupational exposure.

The Society believes that control methods outlined in the standard are feasible but urges that provision be included for a reasonable period to comply with the standards.

We could not attempt to define what that reasonable period should be; that is, I think, a conclusion that is up to the Labor Department.

MR. TOPOL: Okay. I appreciate that.

My point is, I am getting beyond that. I am saying assume that unlimited amount of time so that we remove the time factor.

My question is: what is your basis for concluding that it is technologically feasible for industry to get to the levels in the proposed standard even with an unlimited amount of time?

DR. QUIGLEY: The basis for that conclusion is that there is presently instrumentation available that will detect even lower levels of vinyl chloride.

Now, the -- and we mentioned this, the design, the

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engineering design difficulties in applying those types of instrumentation to the particular environment in which the workers are operating, is another problem.

MR. TOPOL: Okay --

DR. QUIGLEY: And that needs work and research and development.

MR. TOPOL: Okay, I want to move away from the instrumentation design.

That is the question. Can you design equipment to detect very, very small levels? Now leaving that to one side, my question though is;

What is your basis for concluding or maybe you haven't concluded that the industry can get the very low levels that are proposed in the standard?

In other words, that they can make the engineering changes to essentially get to a work environment that has those levels of exposure.

Do you have any basis for concluding that that is technologically feasible given unlimited time?

DR. QUIGLEY: Other than as I stated before, all of these ramifications of the problem were discussed at some length and in some depth by the participants in the deliberation and they in their professional experience, which includes a great deal of industrial experience, reached the conclusion that it is technically feasible to reach this level of

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standard.

MR. TOPOL: Okay. Would you submit -- two questions. First, was there any data assembled for purposes of reaching that conclusion other than these gentlemen's views?

DR. QUIGLEY: As I stated before, sir, there were no lengthy studies conducted by the Society.

The Society draws on the experience and the resources of the experts among its membership to make these recommendations and so whatever data, individuals who are involved had after exposure, whatever experience they had in these areas, was applied to this problem at that particular time.

MR. TOPOL: Were any of these individuals employed by or representing polyvinyl chloride manufacturers?

MR. FAWCETT: Yes.

DR. QUIGLEY: Yes, sir.

MR. TOPOL: Who were those individuals?

MR. FAWCETT: Should we specify names?

DR. QUIGLEY: Well, I think there is no reason why the list of all the individuals of the committee can't be involved because they are a matter of public record.

MR. TOPOL: Would you make available along with the names, the committee members, the meetings where this subject is discussed or the portion where it relates to this subject

are discussed?

MR. FAWCETT: Sure.

MR. TOPOL: Could you identify for me --

JUDGE WYATT: No, they are going to make available, that all you are going to do is prolong it.

MR. TOPOL: Judge Myatt, this is my final question --

JUDGE MYATT: I have been waiting for the final question.

MR. TOPOL: Might I explain, your Honor, if we can have the identification which the individual has now, it is perhaps possible to respond.

JUDGE MYATT: If they are going to submit it for the record, you can get it then.

MR. TOPOL: Your Honor, I can't then put on any other testimony or any rebuttal to that because it will be after the hearing is closed.

JUDGE MYATT: I hope any rebuttal you are going to have is going to be by way of submission.

MR. TOPOL: Well, perhaps someone else, an interested party is listed as a witness could respond to that testimony if it has -- depending on what the testimony is.

JUDGE MYATT: I am not going to debate it with you any more.

MR. TOPOL: Thank you.

MR. MILLER: Marshall Miller, representing Diamond

Shamrock.

Dr. Quigley, A couple of questions to clarify the record. Perhaps if I didn't understand it, perhaps everybody else didn't, either.

Did you poll the members of this Society, coming to this conclusion or was it based solely on a conclusion by the committees?

DR. QUIGLEY: Well, you know, no organization is perfect and as Mr. Fawcett said, I am sure that when the testimony of the American Chemical Society hits the streets, whether in the Washington Post or CDM, that there going to be protests from among our membership.

No, we did not poll the membership. We do not operate through a referendum system.

The bylaws of the Society state that only one that can speak for the American Chemical Society is the Board of Directors.

So we operate organizationally through a system of committees. Just like many other organizations do and the committees, the membership of the committees are appointed by the President of the Society and the Chairman of the Board of Directors.

We have our own Board council committees. These, the members of these committees, are duly authorized to deliberate within the area of cognizance of those particular

committees and it is a consensus process and as you know, a consensus process is not a complete process.

I am not saying that the statement and the testimony is, and has the unanimous support of the American Chemical Society membership, but it has been approved by duly authorized bodies of the Society.

So that, this is a little elaboration on your question, but I thought it would help to put it in perspective.

MR. MILLER: So as I understand it then, the members do not elect the people on the committees. They are appointed by the officers --

JUDGE MYATT: Don't recapitulate. He said and we understand it and it is in the record.

MR. MILLER: Then you will not have any idea how the members themselves feel about this, the cards and letters that have been coming in, is that correct; do I understand you there?

I meant it in an unscientific way. You wouldn't understand until then.

DR. QUIGLEY: Let me put it this way.

That the statement as presented here was approved without dissent by any of the 15 members of the board of directors.

MR. MILLER: When was that; does this testimony reflect developments that have come out in these hearings or

was it approved before?

DR. QUIGLEY: This testimony was prepared for the original date of the hearing. It was ready the first date of the hearing.

MR. MILLER: So we are not taking into consideration that which was involved with Dow --

DR. QUIGLEY: It has not been modified since the Board approved the original testimony.

MR. MILLER: Okay, thank you.

DR. QUIGLEY: What you hear, heard here today, it was not influenced by any testimony that was presented in the hearing so far.

MR. MILLER: Thank you.

JUDGE MYATT: Yes, sir?

Identify yourself.

MR. BOGESE: Steve Bogese, Virginia Plastics.

You mentioned continuous monitoring as one of the recommendations for the OSHA standards.

Did you intend to include the small fabricators in your general statement to be continuously monitored, the whole plant?

I assume, is that correct?

DR. QUIGLEY: I think the reference to continuous monitoring was in relation to the preliminary survey that EPA took of a number of industrial plants.

MR. BOGESE: Yes, but this is a standard. They don't put in. I am asking you, do you recommend that for all fabricators, especially the small ones?

DR. QUIGLEY: The Society's position, sir, is in support of the standard as proposed by OSHA.

MR. BOGESE: Let me ask you this. Did you make economic study of these small fabricators to see if they were capable of doing this?

DR. QUIGLEY: No, sir, we did not. There were no economic or cause effects.

MR. BOGESE: I am a small fabricator and I would say that we could not comply with that without going out of business.

So I would object to this particular --

JUDGE MYATT: Mr. Bogese, you are the next person up here on the platform and I will allow you to voice any objection you want to at that time.

MR. BOGESE: All right, sir, thank you.

JUDGE MYATT: Any other questions?

MR. BECKER: William Becker, B.F. Goodrich.

A question of clarification. I think your statement talked about the approval of part of the standard that has to do with wearing impervious clothing.

I was wondering if your committee had any data concerning heat stress or any other effect of wearing clothing

over eight hours a day.

MR. BECKER: Thank you.

JUDGE MYATT: Any other questions?

MR. KLINE: Your Honor, if I might make a request, would you mind making that article available to the Department of Labor in posthearing conference?

MR. FAWCETT: The article is in a book. The book can be purchased from the Tom Wylie Company in New York City and the exact title of it for the record, Safety and Accident Prevention in Chemical Operations by Fawcett and Wood, W-o-o-d is the second name, Wood, published by Inter-Science Division, John Wylie & Company, 1965, Chapter 23, pages 373 to 428.

That is the exact citation, sir, and I frankly don't have a copy at the moment to give you because I have given them all away to other worthy charities that came down the road a long time ago.

JUDGE MYATT: Are there any other questions?

MR. STEELE: Arthur B. Steele, Union Carbide.

Doctor, I have been a member of the American Chemical Society for 35 years and worked in this industry for more than 30 years.

Would I qualify as one of those membership resources to which you constantly refer?

DR. QUIGLEY: Yes, sir, I would hope so.

MR. STEELE: Would your record show that at any time your organization or your committee sought advice and counsel from people who have the kind of experience that I represent?

DR. QUIGLEY: Yes, sir. One of -- if the Judge will permit me.

One of the problems of a volunteer organization is finding out the knowledgeable volunteers.

I would be very happy to record your name, sir.

MR. STEELE: You would know that the American Chemical Society, together with other agencies of Government mantains a constant roster of p rofessional talent.

DR. QUIGLEY: Yes, sir, we know that.

MR. STEELE: I assume that you used that in trying to bring together a knowledgeable group to bring about this particular position?

DR. QUIGLEY: Yes, sir.

MR. STEELE: I would like you to be advised before you receive letters that I disagree totally with the ACS proposal in this matter and that I would be very glad to join your committee at any time to document the evidence on which I take my position.

DR. QUIGLEY: Yes, sir.

JUDGE MYATT: Any other questions, statements or positions and other testimony from the floor?

United States Department of Labor
Occupational Safety and Health Administration
[illegible] STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL
[illegible]
[illegible] Dec. 7, [illegible]
[illegible] 1974 thru 1994

E R R A T A S H E E T

PAGE NO.	LINE NO.	Correction
4447-8	[illegible]	Add Exhibit No. 32 before No. 33 page 2367
2369	2	Change "matters" to "matters"
2369	3	Change "physican" to "physical"
2369	5	Change "Vinyl" to "vinyl"
2369	15	Change "Before" to "before"
2369	[illegible]	Change "Been" to "been"
2369	19	Change "which" to "while"
2369	21	Change "exposure" to "exposure"
2369	2	Change "death" to "death"
2369	29	Change "indicate" to "Indication"
2369	2	Change "are" to "OSHA has"
2369	[illegible]	Delete 4 words after "to" and substitute "[illegible] and provide adequate protection [illegible]"
2369	[illegible]	Add "trace" after "Nil"
2370	4	Add "a" after "on"
2370	6	Change "evaluation" to [illegible]
2370	15	Change "can" to "cans"
2370	[illegible]	Change "solid undetected" to "[illegible] mine (phosphate)"

1334	1	Change "but" to 'about"
1335	20	Change "company." to "industry."
1335	24	Change "chemical industry." to "discipline of chemistry."
1336	6	Change "polymyzerable to "polymerizable"
1336	9	Change "materials to committee"
1336	16-17	Change "combustion" to "combustible"
1336	23	Change "nature of the" to "major"
1338	7	Change "justified" to "testified at"
1338	21	Change 'in all the" to ", all with"
1341	7	Change "epidemology" to "epidemiology"
1342	21	Change "and" to "hand"
1343	20	Change "Technical" to "Chemical"
1343	24	Change "news" to "News"
1344	3	Change "news" to "News'
1344	8	Change "and" to 'in'
1350	9	Change "and" to "in"
1352	8 & 10	Change "Alveolarosis" to "Brilliosis"
1353	11	Change "of" to "to"
1354	5	Change "produces" to "induces"
1354	10	Change "What" to "One"
1354	25	Change "technically" to "technologically"
1357	11	Change "after exposure" to "at their disposal"
1357	24	Insert "of" after "names," and change "meetings" to "minutes"

1357	25	Change "is" to "was"
1359	11	Change "CDC" to "C&EN" and add "is" after "there"
1362	2	Change "don't" to "going to"
1363	19	Change "where" to "to wear"
1364	17	Change "things" to "tanks"
1365	8	Change "Tom" to "John"
1366	2	Add "monomer" after "chloride"
1366	15	Change "1944" to "1974"
1370	10	Change "would" to "wouldn't"
1372	20	Change "quite filtered" to "non-flammable"
1373	17	Change "intermediate" to "immediate"
1375	20	Add "chloride" after "vinyl"
1375	10, 17 & 24	Change "nitrosamines" to "nitrosoamines"
1376	6	Change "respect" to "prospective"
1379	12	Change "were seeing" to "receive"
1380	6	Change "atmosphere" to "as compared"
1380	19	Change "or Canada," to "in Canada,"
1381	12	Change "fact" to "factor,"
1382	28, 29	Change "Robotek" to "Robintech"
1403	23	Change "situation" to "situation"
1429	17	Change "chronic" to "chronic"
1426	7	Change "known technical" to "non-toxic"
1430	4	Change "clause" to "cause"
1430	12	Insert "other" after "those"
1430	13	Change "various" to "variance"

112.

July 26, 1974

H. E. Everson
6123 Campbell Drive
North Madison, Ohio 44057

Occupational Safety & Health Administration
Department of Labor
1726 M Street, N.W., Room 200
Washington, D.C.

Re: Docket OSH-36

Atten: Mr. Julius Jimeno

Dear Sir:

As a member of the American Chemical Society, I wish the record in the above captioned matter to reflect my disagreement with the position taken by the American Chemical Society at the recent vinyl chloride hearings. I am familiar with PVC manufacturing operations, having been associated for many years with a company producing various grades of PVC resins. The major point of my disagreement with testimony given by the American Chemical Society witnesses is with their expressed position that it is feasible to operate a PVC plant under the restriction of a "no detectable" limit of worker exposure to vinyl chloride monomer. It is my opinion that it is neither feasible nor necessary to operate under such a limitation. The complexity of a PVC manufacturing plant is such that it is not possible to prevent some vinyl chloride monomer from escaping into the workplace atmosphere.

I believe that the exposure limits as proposed by the Society of Plastics Industry in its testimony is reasonable and achievable and should be adopted as a part of a permanent standard for vinyl chloride monomer.

Very truly yours,

H. E. Everson

Howard E. Everson, Ph.D.

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July 24, 1974

Mr. Julius Jiveno
OSHA (Room 203)
Dept. of Labor
1726 H Street, N. W.
Washington, D. C.

Dear Sir:

Subject: Docket OS 836

I am a member of the American Chemical Society. The ACS does not represent me in the position taken with respect to vinyl chloride exposure limits and protective measures. I have not been contacted or polled concerning this question.

As an employee of a PVC manufacturing firm, my view may be biased. My twenty years working with PVC and vinyl chloride, however, would seem to qualify me as an expert witness. I enjoy good health. A recent plant-wide physical revealed no indication of liver cancer in myself or any other worker in the PVC plant where I am employed.

I think it is important to minimize exposure to vinyl chloride or any other chemical. I am obviously opposed, however, to setting the limits so low that manufacture becomes impossible or impractical.

Sincerely,

Clifford N. Miller

Clifford N. Miller
10914 Arrendale
Houston, Texas 77034

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DIAMOND SHAMROCK CORPORATION

T. R. EVANS RESEARCH CENTER • P.O. BOX 348 • PAINESVILLE, OHIO 44077 • 216/352-9311

July 24, 1974

Mr. Julius Timino
Occupational Safety and Health Administration
1726 M St., N.W.
Room 200
Washington, D.C.

Dear Mr. Timino:

I recently read the testimony in CHEMICAL & ENGINEERING NEES, July 15, 1974, page 4, stating the American Chemical Society's position regarding strict vinyl chloride limits, as presented by Howard H. Fawcett, chairman of the ACS Committee on Chemical Safety and Dr. Stephen T. Quigley, head of the Society's department of chemistry and public affairs.

I have been a member of the American Chemical Society for over 20 years, and to my knowledge, this is the first time that the Society has taken such an unscientific position. ACS is an organization whose major purpose is the technical and scientific advancement of chemistry and chemical engineering. I found it very disconcerting that they had taken a position on an area which obviously needs a great deal of additional study before any definitive conclusions can be drawn.

I certainly support them in their recommendations on

a. practical standards
b. reasonable time to meet these new standards
c. continuous monitoring
d. additional study of protective equipment.

However, I heartily disagree with their call for "no detectable level."

I have been intimately involved with industry's environmental problem, and it is my view that the position of a no detectable limit is absurd. What is a detectable limit? The ability to achieve the feasible technology to overcome any serious health hazard is the object of the majority of the workers in industry, including myself. I also submit that the committee does not speak for the membership of the American Chemical Society.

As far as my personal background to comment on this subject, I have a PhD degree and have been involved in research activities both in government, with the Chemical Corps, and with Diamond Shamrock Corporation's analytical department for my total professional career. I have been associated very closely over the past ten years with physical properties and analytical methods relating specifically to plastics. I therefore feel that it is wrong for the Society to take up what is obviously not their responsibility. It is necessary that all facts should be in before any firm and definitive conclusions are reached.

Sincerely,

Kevin J. O'Leary,
Associate Director,
Electrochemistry

dho

1487

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Diamond Shamrock Chemical Company
Plastics Division / 1100 Superior Avenue / Cleveland, Ohio 44114 / Telephone (216) 621-6100

July 22, 1974

Occupational Safety and Health Administration
Department of Labor
1726 M Street N.W., Room 200
Washington, D.C.

Attention: Mr. Julius Jimano
Docket OSH-56

Gentlemen:

Subject: Vinyl Chloride Hopower Hearings

The American Chemical Society recently testified that they are in concurrence with the proposed NIOSH recommendations of no detectable level of vinyl chloride monomer.

I have been an ACS member for 21 years and have a Masters degree in organic chemistry. As a member of ACS, I take exception to their testimony. From what I know, I do not believe that the proposed standard can be met, and hence wanted to record my dissent.

Very truly yours,

Richard A. DiBanza
Manager, Sales and Marketing

RAD/et

1488 122

PPG INDUSTRIES, INC./ONE GATEWAY CENTER/PITTSBURGH, PENNSYLVANIA 15222/AREA 412/434-2585

ZEB G. BELL, Jr., Sc.D., Director
Environmental Control, Industrial Chemical Division

July 31, 1974

Mr. John Stender
Assistant Secretary
Department of Labor
Room 3115
14th and Constitution Avenue, N.W.
Washington, DC 20210

Dear Mr. Stender:

The reason for this correspondence is to express my objection to the position taken by the American Chemical Society on the proposed permanent standard for vinyl chloride presented at the Public Hearing in Washington, DC.

The past president of AIHA requested in a telephone conversation that I represent the Association at the American Chemical Society meeting scheduled for May 21, 1974, on vinyl chloride. I received a confirming letter dated April 26 thanking me for consenting to represent the AIHA (Enclosure No. I). On April 29, 1974, Mr. H. H. Fawcett sent me a letter and additional correspondence (Enclosure No. II).

The American Chemical Society ad hoc Task Force met on May 21, 1974. The basic questions confronting the ACS were:

1) Should the Society take a position on the proposed standard?

2) Is VCM the chemical that has caused the problem?

3) In the opinion of the Society, is the proposed standard reasonable and appropriate?

The ad hoc Task Force on Vinyl Chloride had only two members currently employed in industry--myself (representing AIHA) and Mr. George Wilson of Firestone Tire and Rubber (representing the ASTM, E-34).

The attendence at the ad hoc Task Force meeting on May 21 is shown in Enclosure No. III.

The outgrowth of this meeting was a draft of a position to be taken by the Society (Enclosure IV - May 23, 1974, cover letter from H. H. Fawcett and copy of first draft). This draft addressed itself to the basic rationale used in setting the proposed standard and not directly to the specifics of the proposed standard. Further, this draft did not indicate any endorsement of the proposed "non-detectable" level concept nor was technical feasibility discussed at the May 21, 1974, meeting. Upon review of the draft position by the Society, I had no major objections.

In the subsequent correspondence package from the Society (Enclosure No. V - transmittal letter from Mr. Halley Merrell, dated June 12, 1974, and from Mr. S. T. Quigley, dated June 7, 1974), it can be seen that a deadline of 5:00 p.m., June 12 was set for comments on the third revision of the draft. However, this draft was received in my office on June 13, 1974. Concurrently, I was on vacation during that entire week. In addition, the accompanying cover letter stated: "It would likely be helpful if the ad hoc Task Force and CCS members were on record as recommending Board approval of the statement. If you approve the statement, may I request that you telephone me immediately." I did not telephone approval.

Through retrospective deduction, I must assume there was a second draft which I did not receive or review.

Because of my extensive traveling, a recent bereavement, and a presumption that subsequent drafts would not deviate substantially from the original draft, I did not appreciate the substantive changes that were incorporated in the latest draft or the final testimony given by the American Chemical Society.

I was given no further opportunity to review the final position taken by the American Chemical Society nor was any other meeting of the ad hoc Task Force members called before the final position was presented at the Public Hearing.

I personally cannot support the final position taken by ACS nor do I believe that it is proper to necessarily imply that the AIHA endorses the American Chemical Society's position.

Very truly yours,

Zeb G. Bell, Jr.

ZGB:mal

Attachments

cc: Daniel Boyd - OSHA
Howard H. Fawcett - National Academy of Sciences
Paul Halley - Standard Oil Co.
Jerome H. Heckman - Keller and Heckman
Edward Kline - Office of the Solicitor
Donald Lassiter - OSHA
William E. McCormick - AIHA
John A. Pendergrass - AIHA
Stephen T. Quigley - ACS
Jerome T. Siedlecki - AIHA
W. Mayo Smith - Air Products
Henry Stremba - ASTM
George L. Wilson - Firestone

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ENCLOSURE NO. 1

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BERNARD D. TEBBENS, Sc.D.
UNIVERSITY OF CALIFORNIA

REPLY TO:

April 26, 1974

Zeb C. Bell, Jr., Sc.D.
Pittsburgh Plate Glass Co.
1 Gateway Center
Pittsburgh, Pennsylvania 15222

Dear Zeb:

Thank you for accepting to represent AIHA on the American Chemical Society Ad Hoc panel meeting and vinyl chloride. The meeting is scheduled at 9:30 AM, May 21, 1974 in the ACS Building, 1155 16th St., NW, Washington, D.C. Howard Fawcett will contact you regarding any further arrangements. Enclosed is correspondence from Howard regarding the meeting.

Sincerely,

Jerome T. Siedlecki
President

mz
Enclosures

cc: H. H. Fawcett
J. A. Pendergrass
W. E. McCormick

RECEIVED
MAY 2 1974
MFG. DIV.

NATIONAL RESEARCH COUNCIL
NATIONAL ACADEMY OF SCIENCES NATIONAL ACADEMY OF ENGINEERING
WASHINGTON, D.C.
COMMITTEE ON HAZARDOUS MATERIALS
TELEPHONE: 202 961-1579
CABLE ADDRESS: NARECO, WASHINGTON, D. C.

18 April 1974

RECEIVED
IND HYG

Mr. Jerome T. Siedlecki
Director, Industrial Hygiene
Standard Oil Company (Indiana)
200 E. Randolph Drive
Chicago, IL 60601

Dear Jerry:

Confirming our telephone conversation this afternoon, I would be most grateful if you or someone you designate would represent the A.I.H.A. at an ad hoc panel meeting concerned with standards for vinyl chloride in the context of the American Chemical Society. For your information, I am enclosing two documents dated April 1, 1974 and April 15, 1974 which indicate the task at hand. I have asked Dr. V. C. Brum to chair this one-day meeting which we have scheduled for May 21 starting at 9:30 a.m. in the American Chemical Society building, 1155 16th Street, NW, Washington, DC.

It is my hope that by assembling a small group of eminently qualified and scientifically objective individuals we can develop a statement for the American Chemical Society to ultimately present to the Department of Labor.

If you could let me know as soon as possible by telephone who you feel can best represent the A.I.H.A. at this meeting, I would be extremely grateful.

Kindest personal regards,

H. H. FAUCETT
Technical Secretary

HHF:rj
Enclosure
cc: Dr. V. C. Brum
Mr. H. Merrell

ENCLOSURE NO. II

1438

NATIONAL RESEARCH COUNCIL

NATIONAL ACADEMY OF SCIENCES NATIONAL ACADEMY OF ENGINEERING

WASHINGTON, D.C.

COMMITTEE ON HAZARDOUS MATERIALS

TELEPHONE: 202 961-1579
CABLE ADDRESS: NARECO, WASHINGTON, D. C.

29 April 1974

Dr. Zeb Bell
P.P.G. Industries
1 Gateway Center
Pittsburgh, PA 15222

Dear Dr. Bell:

This is to confirm the telephone conversation we had Friday in which we discussed your participation in the American Chemical Society ad hoc review of vinyl chloride standards scheduled May 21, 1974 in Washington, DC. So you will have the same background as the other invited conferees, I am sending you the original letter to them as well as the attachments from Dr. Quigley which prompted our action.

By copy of this letter, I am thanking Mr. Siedlecki for his kindness in "volunteering" your services and also informing Dr. Brum, the chairman, that you will be present as a representative of the A.I.H.A. Meanwhile we are looking forward to meeting you at the meeting in New York, May 10 and 11.

Sincerely yours,

H. H. FAWCETT
Technical Secretary

HHF:rj

cc: Mr. J. T. Siedlecki
Dr. V. C. Brum

Enclosures

RECEIVED
MAY 2 1974
MFG. DEPT.

AMERICAN CHEMICAL SOCIETY

COMMITTEE ON CHEMICAL SAFETY

22 April 1974

MEMORANDUM

To: Dr. V. Brum, Veterans Administration
Mr. Jeremiah Lynch, N.I.O.S.H., (A.C.G.I.H.)
Mr. John Mark, National Safety Council
Dr. McNamara, Edgewood Arsenal
Dr. Nina McClelland, National Sanitation Foundation
Dr. E. Shepard, A.C.S. Committee on Membership Affairs
Dr. Elizabeth Weisberger, National Cancer Institute
Dr. F. A. Van Atta, O.S.H.A., Department of Labor
Mr. Jerome T. Siedlecki, President, A.I.H.A.
Mr. Paul Halley, Chairman, A.S.T.M.
Mr. Ralph Wands, National Research Council Advisory Center on Toxicology
Mr. George White, National Research Council Committee on Hazardous Materials

From: Mr. H. H. Fawcett, Chairman, A.C.S. Committee on Chemical Safety

Subject: Meeting of Ad Hoc Panel of Experts to evolve and recommend A.C.S. position on exposure to Vinyl Chloride Monomer

At the American Chemical Society Committee on Chemical Safety meeting held at Los Angeles, April 1, 1974, a formal request was received from Dr. Quigley of the A.C.S. Executive Office for comments as noted in the April 1 letter attached. The Committee on Chemical Safety, while recognizing both the serious nature and urgency of the request, noted unanimously to assemble a small ad hoc panel of experts from within the A.C.S. who had specific knowledge and experience to help formulate the A.C.S. position requested by Dr. Quigley.

Subsequently, the Federal Register for April 5 lowered the TLV of VCM to a ceiling of 50 ppm, and noted that a permanent value would be established shortly.

Under date of April 15, Dr. Quigley wrote further (enclosed) concerning the task.

Dr. V. C. Brum, who has graciously agreed to chair this ad hoc panel, has asked me to invite you, or someone from your group who has specific knowledge of VCM (obviously including but not restricted to the angiosarcoma problem), to a one-day meeting which is scheduled for 9:30 a.m. EDT Tuesday, May 21, at the American Chemical Society Building, 1155 16th St., Washington, D.C. At this meeting, the specific scientific facts will be reviewed (including the detailed reports which the New York Academy of Sciences will review at their May 10-11 meeting on VCM, PVC and related substances), and an attempt will be made to draft a

statement for submission to Dr. Quigley, as he requested.

Unfortunately, no funds have been made available for this meeting, so we must ask participants to defray their own expenses for travel and lodging. Lunch will be served as part of the meeting.

Will you please let me know by return mail whether or not we can expect you, or some knowledgeable person whom you designate, to attend this meeting, or as an alternative, call me at 202-389-6579.

It is our wish to keep attendance as limited and selected as possible, to achieve a maxiuum input in the very severe restraints of time which have been imposed. Therefore, we respectfully request you consider attendance at this meeting by invitation only. No attempt will be made to restrict scientific objectivity or complete factual data, however, which, of course, is the prime purpose of the meeting.

Your cooperation in this endeavor will be much appreciated by Dr. Quigley and Dr. Brum, as well as by me.

Most respectfully,

H. H. Fawcett

Howard H. Fawcett
Chairman, A.C.S. Committee on
Chemical Safety

address for reply:
H.H. Fawcett
National Academy of Sciences
2101 Constitution Ave., N.W.
Washington, D.C. 20418

cc: Dr. S. T. Quigley, A.C.S., 1155 16th St., N.W. Washington, D.C.
Mr. Halley Harrell, A.C.S., 1155 16th St., N.W. Washington, D.C.
Dr. Henry Hill, Riverside Research Laboratory, Ward-Hill Industrial Center
300 Rock Road, Haverhill, Massachusetts 01830

American Chemical Society

DEPARTMENT OF CHEMISTRY
AND PUBLIC AFFAIRS

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4600

April 15, 1974
120-227-74

MEMORANDUM

TO: Mr. H. H. Fawcett

FROM: S. T. Quigley

SUBJ: OSHA Emergency Temporary Standard for Exposure to Vinyl Chloride

I have enclosed a copy of the published emergency temporary standard for exposure to vinyl chloride previously described in my memoranda of March 29, 1974 (120-02LA-74) and April 1, 1974 (120-03LA-74). Since the petitions for an emergency standard requested that the standard be based on the recommendations of the Standards Advisory Committee on Carcinogens, I have enclosed a copy of those recommendations as published in the Federal Register.

You will note that a rulemaking proceeding will soon be initiated to develop a "permanent" standard. A proposed rule is expected to be published by April 19, 1974. It is based on the emergency standard and is more complete than the emergency standard in that it addresses the fire hazards of vinyl chloride as well as its toxicological properties.

Once the proposed "permanent" rule for exposure to vinyl chloride is published, I shall forward a copy. A period of 60 days from the date of publication is generally provided for submission of comments to the Department of Labor. Thus, assuming publication of the proposed rule by April 19, 1974 as expected, a tentative date of May 20, 1974 would be convenient for receiving the recommended comments of the Committee on Chemical Safety to allow coordination with any recommendations of the Committee on Environmental Improvement prior to transmitting a draft statement to the ACS Board of Directors for approval.

If you have any questions regarding this matter, please contact this office.

Enclosures (2)

S. T. Quigley (ENJK)

cc: Dr. V. C. Brum
Dr. R. M. Cairns
Dr. R. L. Kenyon
Dr. T. E. Larson
Mr. H. A. Merrell
CEI subcommittee to develop a model protocol in setting regulatory standards:
Dr. D. G. Crosby, Chairman
Dr. E. V. Kloker
Dr. D. MacDougall
Dr. T. F. Yo[illegible]

Pp. 12342 - 12344

1497

Title 29--Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Emergency Temporary Standard for Exposure to Vinyl Chloride

1. *Background.* Vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014, is a synthetic chemical made by oxychlorination of ethylene or by hydrochlorination of acetylene. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping tissues, electrical insulation, pipe, conduit and a variety of other products. Vinyl chloride has been made commercially in this country since 1939 and present production is in excess of seven billion pounds per year.

Vinyl chloride (VC) is a gas at ambient temperature and pressure and is a chlorinated hydrocarbon which has moderate liver toxicity. The present standard sets a ceiling value of 500 parts per million (ppm) (29 CFR 1910.93).

On January 22, 1974, the Occupational Safety and Health Administration was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company reported that deaths of several of its employees from a rare form of liver cancer may have been occupationally related. As a result of this notification, and after consultation with NIOSH and a joint inspection of the plant by OSHA, NIOSH, and the Kentucky Department of Labor, a fact-finding hearing on possible hazards involved with the manufacture and use of both VC and polyvinyl chloride was announced on January 30, 1974 (39 FR 3674), and held on February 15, 1974.

2. *Carcinogenicity of VC.* Information produced at the hearing demonstrated that exposure of laboratory animals (mostly Sprague-Dawley rats) to VC by inhalation at and below the current OSHA standard of 500 ppm induced tumors, principally angiosarcomas of the liver. Professor Cesare Maltoni, of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure of rats, mice, and hamsters to VC at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 ppm for various periods of time (TR 53-63). Some of the experiments have been concluded, and others are still on-going. The experimental results to far reported are that tumors have been observed in groups of animals exposed to VC at concentrations as low as 250 ppm. No tumors have been observed in the group of animals exposed to VC at a concentration of 50 ppm. It also appears so far that the total number of tumors, as well as the numbers of angiosarcomas of the liver, decrease as the concentrations of VC are reduced to 250 ppm. Finally, another experiment by Professor Maltoni is underway involving the exposure of 300 animals to VC at concentrations of 50 ppm, in order to assess in a more definitive way whether that level of exposure produces tumors in animals. Data reported by Torkelson, Oyen and Rowe (American Industrial Hygiene Association J 22:354-361 (1961)) indicate that exposure to VC at concentrations of 50 ppm failed to induce tumors in rats, hamsters, rabbits, and dogs.

The employees of the B. F. Goodrich Chemical Company who died from angiosarcoma of the liver had an average exposure of approximately 19 years to vinyl chloride, at unknown concentrations, and variable exposures to other volatile chemicals. (TR 93). Some employees of Union Carbide Company and Goodyear Company are also reported in a post-hearing comment from NIOSH dated March 11, 1974, to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed that liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals. It is concluded therefore, that vinyl chloride is carcinogenic for humans.

We therefore conclude that the present standard for VC should be lowered from a ceiling of 500 ppm to a ceiling of 50 ppm for the following reasons:

(a) In light of the evidence referred to above including the Maltoni experiments demonstrating that VC is carcinogenic in animals at 250 ppm, we conclude that VC must be considered carcinogenic in man at the same level;

(b) Although Professor Maltoni did not induce tumors in his experimental animals at an exposure concentration of 50 ppm, these data do not support the concept that occupational exposure of employees to concentrations of 50 ppm throughout their working lifetime would be without detrimental health effects;

(c) The question whether safe levels of exposure to carcinogens exist for humans and, if so, what such levels would be, is the subject of continuing scientific deliberation. In the case of VC, Professor Maltoni did not observe tumors in his animals at exposure concentrations of 50 ppm. In addition, Torkelson, Oyen, and Rowe found that exposure to concentrations of 50 ppm of VC failed to induce tumors in rats, hamsters, rabbits, and dogs. Accordingly, there is insufficient evidence at this time to conclude that VC at concentrations of 50 ppm or below poses a grave danger to humans.

(d) The emergency temporary standard adopted today effects a substantial reduction in the permissible level of exposure and, in our practical judgment, is the lowest level that can be complied with immediately; and

(e) This standard will be in effect for a period of no longer than six months, during which time the whole question of possible safe exposure of humans to VC will be reconsidered more fully and in the light of more information, including experiments which are under way at this time (TR 37, 69, 71-73).

3. *Petitions for an emergency temporary standard.* In a telegram to the Assistant Secretary of Labor, received on or about March 14, 1974, the President of the United Rubber Workers International Union urged the establishment of an emergency temporary standard for VC. During the hearing of February 15, 1974, the Industrial Union Department, AFL-CIO, and the United Rubber Workers International Union made a joint petition for an emergency temporary standard for VC (TR 141-148), which was also joined by the Oil, Chemical and Atomic Workers International Union (TR 37). At the same hearing, several participants urged, on the other hand, a regular rulemaking proceeding as the most suitable for the orderly development of relevant information (TR 112, 180).

The petitions for an emergency temporary standard specified in detail the contents of the standard requested. In substance, the request is to issue a comprehensive fully-developed standard based on the recommendations of the Standards Advisory Committee on Carcinogens submitted to the Assistant Secretary of Labor on or about August 27, 1973. The recommendations are far-ranging, and cover special categories of operations, signs and labels, medical surveillance, reporting, etc., including a permit system for the use of a carcinogen.

We agree that an emergency temporary standard is necessary. We cannot say on the basis of the information developed so far that a comprehensive standard, such as the one requested, is either necessary or even desirable. It has been decided to promulgate a standard containing only those essential provisions which are deemed necessary to provide protection to employees from grave danger until a regular rulemaking proceeding in accordance with sections 6 (b) and (c) of the Act can be concluded. The reasons for a decision to establish a ceiling value of 50 ppm have already been stated. A decision on other possible, appropriate provisions is best made after consideration of all relevant data and views that interested persons may submit during the proceeding soon to be initiated.

With respect to arguments in opposition to issuance of an emergency temporary standard, the concern and effort of several companies, particularly since the hearing, for the protection of their employees are recognized. It may also be that some employers in some plants have fully complied with the interim controls recommended by NIOSH on January 30, 1974. There is however reason to believe that employees are currently being exposed to VC at concentrations well above 50 ppm. This was asserted several times at the hearing, and not seriously disputed. Moreover, a report, dated March 1974, of a survey by the Bureau of Occupational Safety and Health Development, Ohio Department of Industrial Relations, involving 30 rigid polyvinyl chloride resin/compounding plants, found that employees in 20 of the plants were exposed to VC at concentrations in excess of 50 ppm. Eight of the plants had employees exposed to VC at concentrations in excess of 500 ppm. Three plants had employees exposed to VC at concentrations in excess of 1,000 ppm. Two plants had employees exposed to VC at concentrations in excess of 2,000 ppm. Finally, one plant had employees exposed to VC at concentrations in excess of 3,000 ppm. Thus, the data indicate that many employees are exposed to VC at concentrations in excess of 50 ppm, and that many employees are exposed to VC at concentrations in excess of 500 ppm. Therefore, it is believed necessary to provide immediately adequate protection to workers by

posed to VC. Also, the eight-hour, time-weighted average standard suggested by several participants at the hearing (see, for instance, Tr. 178), has been rejected. The March 1974 report of the survey revealed that several kinds of work or operations are of short duration. Loading or unloading of a tank car may require approximately 15 minutes. The cleaning of a reactor may require approximately half an hour. An eight-hour, time-weighted average standard would permit exposure to VC at concentrations of 400 ppm for one hour. Such upward excursions, several times the 50 ppm level, cannot be permitted to occur.

b. 4. *The standard.* The standard set out below contains only the requirements deemed necessary to provide protection before the conclusion of the rulemaking proceeding to be commenced shortly.

Because exposure to VC is hazardous, and because such exposure can occur in the processes of synthesizing or polymerizing of VC or in the handling of VC polymers or copolymers which contain absorbed VC, this standard applies to all such processes and to the handling, reacting, manufacturing, processing, releasing, reloading, and storage of any of these materials. The monitoring requirements serve two purposes, to trigger into operation a compliance program and to check the effectiveness of the program. Also, engineering controls are favored for compliance, and respirators are intended to provide protection until such controls can be installed or in case where such controls are not feasible.

Accordingly, by reason of the foregoing and on the basis of the record of the hearing of February 15, 1974, with exhibits, the written submissions received before the hearing pursuant to the notice of the hearing, the post-hearing written submissions by the participants at the hearing, the March 1974 report of a fact-finding survey recommendations received from NIOSH, and the other data referred to herein, it is found (1) that VC at concentrations in excess of 50 ppm is physically harmful and carcinogenic; (2) that exposure to VC at concentrations in excess of a concentration of 50 ppm poses a grave danger to employees; (3) that employees are presently exposed to VC at concentrations in excess of 50 ppm; and (4) that this emergency temporary standard set out below is necessary to provide immediate protection to employees from such danger.

Pursuant to section 6(c) of the Occupational Safety and Health Act of 1970, a proceeding will commence shortly in accordance with section 6(b) of the Act, in which this emergency temporary standard will serve as a proposed rule, together with other substantive rules. As soon as possible a draft environmental impact statement will be filed with the President's Council on Environmental Quality, and copies will be provided to other appropriate Federal agencies for their comments.

Pursuant to sections 6(c) and 8(g)(2) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1599, (29 U.S.C. 655, 657)), and Secretary of Labor's Order No. 12-71 (36 FR 8754), 29 CFR Part 1910 is amended by adding thereto a new § 1910.93q to read as set forth below. In addition, pursuant to section 4(b)(2) of the Act (84 Stat. 1592; (29 U.S.C. 653)), the standard in the new § 1910.93q is determined to be more effective than the corresponding standard, now in Subpart Z of Part 1910, in Parts 1915, 1916, 1917, 1918, and 1926 of title 29, Code of Federal Regulations, and in Part 50-204 of Title 41 of the Code of Federal Regulations. Therefore, these corresponding standards are superseded by the new standard in § 1910.93q.

1. In 29 CFR Part 1910, § 1910.93 is amended by deleting from Table G-1 the line: "• • • C Vinyl chloride • • • 500 • • • 1300".

2. Part 1910 of Title 29 of the Code of Federal Regulations is amended by adding thereto a new § 1910.93q to read as follows:

§ 1910.93q Vinyl chloride.

(a) *Scope and application.* (1) This section applies to any area or operation in which vinyl chloride (chloroethene), Chemical Abstracts Service Registry Number 75015, is manufactured, reacted, handled, processed, released, repacked, or stored.

(2) This section does not apply to the handling, storage, or other use of vinyl chloride polymers and copolymers in the form of fabricated products.

(b) *Permissible exposure.* The occupational environment must be controlled so that no employee is exposed to vinyl chloride at a concentration in excess of 50 parts per million (ppm) (127.6 mg/cu.m.).

(c) *Monitoring.*—(1) *Initial monitoring.* As soon as possible but not later than April 22, 1974, every employer of an employee working in an area or operation in which vinyl chloride is manufactured, reacted, handled, processed, released, repacked, or stored shall begin monitoring the ambient air of the area to determine whether it contains vinyl chloride in concentrations in excess of 50 ppm.

(2) *Frequency.* Monitoring of a sufficient number of employees so that a representative sample of exposures to vinyl chloride may be determined shall be accomplished not less frequently than weekly until all results for three consecutive weeks are at or below 50 ppm. Thereafter, monitoring shall be required at least less frequently than monthly to learn as the concentrations of vinyl chloride do not exceed 50 ppm. If a monitoring result reveals vinyl chloride in concentrations in excess of 50 ppm, weekly monitoring shall be resumed until all results for three consecutive weeks are at or below 50 ppm.

(3) *Method of monitoring.* Personnel monitoring shall be accomplished by collecting samples by suitable devices worn by the employee. The samples shall be analyzed by gas chromatography or by any other method which is of equivalent accuracy. The analytical procedure shall be sensitive to a level of vinyl chloride in air which is accurate to ±10 percent for a ten minute air sample.

(4) *Employee observation of monitoring.* Employees working in an area or operation whose ambient air is monitored, or their representatives, shall be given a reasonable opportunity to observe the personnel monitoring required by this section.

(5) *Recordkeeping.* The results of all monitoring shall be recorded in writing. The records shall be retained for at least 5 years and shall be made available for inspection and copying by representatives of the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health (NIOSH).

(6) *Employee access.* Each employee and former employee shall have access to such records of the results of monitoring required by this section as will indicate his own exposure to airborne concentrations of vinyl chloride.

(7) *Employee notification.* Each employer shall promptly notify any employee who has been or is being exposed to vinyl chloride in concentrations in excess of 50 ppm, and shall inform him of the corrective action being taken.

(d) *Compliance.* (1) Whenever any monitoring sample reveals vinyl chloride at a concentration in excess of 50 ppm, or whenever any accident, such as rupture of equipment or spillage, indicates the likelihood of a greater than usual release of vinyl chloride into the ambient air, all employees exposed to such concentrations shall be withdrawn to and shall not be permitted to enter the work area unless they wear either Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(2) Work which may reasonably be expected to release vinyl chloride in concentrations in excess of 50 ppm, such as repair, maintenance or cleaning of reactors or other equipment containing vinyl chloride, shall be accomplished only by employees wearing Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(3) In any case covered by paragraphs (d)(1) or (d)(2) of this section. In addition to providing the required respirators, the employer shall examine and evaluate the source of the excessive concentrations of vinyl chloride in order to determine feasible engineering or operational controls appropriate to reduce the airborne concentrations to the permissible level. Such controls shall be implemented as quickly as possible.

(4) Periodic tests shall be conducted for equipment leaks and for emissions of vinyl chloride which may result from work practices.

3. In 29 CFR Part 1910, § 1910.16 is revised to read as follows:

§ 1910.19 Special provisions for air contaminants.

(a) *Asbestos, coal.* Section 1910.93 shall apply to the exposure of every employee to asbestos dust in every establishment or place of employment covered by [illegible] § 1910.93, § 1910.93a, § 1910.93b, § 1910.93c, or § 1910.16, in lieu of any dif-

ferent standard on exposure to asbestos dust which would otherwise be applicable by virtue of any of those sections.

(b) *Vinyl chloride.* Section 1910.93q shall apply to the exposure of every employee to vinyl chloride in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, or § 1910.16, in lieu of any different standard on exposure to vinyl chloride which would otherwise be applicable by virtue of any of those sections.

Effective date. These amendments shall become effective on April 5, 1974.

(Secs. 4, 6, and 8, 84 Stat. 1592, 1596, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71, 36 FR 8754.)

Signed at Washington, DC., this 2d day of April 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.74-7890 Filed 4-4-74;8:45 am]

p. 24575

PROPOSED RULES

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1910]

STANDARDS ADVISORY COMMITTEE ON CARCINOGENS

Notice of Receipt of Recommendations of the Committee and of Their Availability for Public Inspection

Notice is hereby given that the Standards Advisory Committee on Carcinogens, established under section 7 of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593), submitted to the Assistant Secretary of Labor for Occupational Safety and Health, on August 27, 1973, its recommendations for a standard for certain carcinogens. The full text of the recommended standard is set forth in an appendix to this notice.

The number appearing in parentheses in the lower right corner of each recommendation records the voting of the Committee members. The first number indicates the affirmative votes, the second number indicates the negative votes, and my third number indicates abstentions.

Copies of the recommended standard will also be made available for inspection and copying, upon request, at the U.S. Department of Labor, Office of Standards, Railway Labor Building, Room 500, 400 First Street NW., Washington, D.C. 20210, and at the following regional offices:

John F. Kennedy Federal Building, Government Center, Room No. 2303, Boston, Mass. 02203; 1515 Broadway, New York, N.Y. 10036; Penn Square Building, Room 623, 1317 Filbert Street, Philadelphia, Pa. 19107; 1375 Peachtree Street NE., Suite 587, Atlanta, Ga. 30309; 300 South Wacker Drive, Room 1201, Chicago, Ill. 60606; Seventh Floor, Texaco Building, 1512 Commerce Street, Dallas, Tex. 75201; 823 Walnut Street, Wallcoser Building, Room 300, Kansas City, Mo. 64106; Federal Building, Room 1049, Post Office Box 3583, 1961 Stout Street, Denver, Colo. 80202; 9470 Federal Building, 450 Golden Gate Avenue, Box 36017, San Francisco, Calif. 94102; 506 Second Avenue, 1206 Smith Tower Building, Seattle, Wash. 98104.

Signed at Washington, D.C. this 29th day of August 1973.

JOHN H. STENDER,
Assistant Secretary of Labor.

APPENDIX

PROPOSED STANDARD FOR CERTAIN CARCINOGENS AS RECOMMENDED BY THE STANDARDS ADVISORY COMMITTEE ON CARCINOGENS AUGUST 27, 1973

§ 1910.[ ] Carcinogens.

(a) *Purpose.*—The purpose of this standard is to prevent any worker contact or exposure to any of the listed carcinogens as detected by the most sensitive feasible sampling and analytical

(b) *Scope and application.*—This section applies to any workplace in which a carcinogen is manufactured, processed, used, repackaged, released, handled or stored, but shall not apply to any workplace involving only shipment of carcinogens in appropriate, sealed containers.

(c) *Terminology.*—For the purpose of this standard: (1) "carinogen" includes one or more of the fourteen substances listed below.

Compound No.	Chemicals	Chemical abstract registry No.
1	2-Acetylaminofluorene	53963
2	4-Aminobiphenyl	92671
3	Benzidine (and its salts)	92875
4	3,3'-Dichlorobenzidine (and its salts)	91941
5	4-Dimethylaminoazobenzene	60117
6	alpha-Naphthylamine	134327
7	beta-Naphthylamine	91598
8	4-Nitrobiphenyl	92933
9	N-Nitrosodimethylamine	62759
10	beta-Propiolactone	57578
11	bis Chloromethyl ether	542881
12	Methyl Chloromethyl ether	107302
13	4,4'-Methylene (bis)-2-chloroaniline	101144
14	Ethyleneimine	151564

(2) "Regulated area" is an area in which there is potential exposure to a carcinogen and where entry and exit shall be restricted and controlled by the employer.

(3) "Decontamination" is the safe removal from the work environment or inactivation of a carcinogen to eliminate residual carcinogen as detectible by the most sensitive, feasible sampling and analytical methods available.

(4) "Disposal" is the safe removal or inactivation of a carcinogen to prevent introduction of the carcinogen into regulated areas, nonregulated areas, or the external environment.

(5) "Feasible" is capable of being accomplished successfully within the best practicable technology as it exists or may develop.

(6) "Closed system" is an operation involving a carcinogen where the containment prevents the release of the carcinogen, as detected by the most sensitive, feasible, continuous sampling and analytical methods available, into regulated areas, non-regulated areas, or the external environment.

(7) "Isolated system" is a fully enclosed structure, which is impervious to the passage of a carcinogen, other than the vessel of containment of the carcinogen, and which would prevent the entry of the carcinogen into regulated areas, non-regulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.

(8) "Laboratory type hood" is a device enclosed on three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving a carcinogen within the hood does not require the presence of any part of any employees' body other than his hands and arms. cf. the American Conference of Governmental Industrial Hygienists "Industrial Ventilation, A manual of Recommended Practice" section on laboratory hoods details and operation when handling and using highly toxic substances, and the section "Hood Design Data."

(9) "Open vessel system" is an operation involving a carcinogen in an open vessel, not in an isolated system, not in a laboratory-type hood, nor in other systems affording equivalent protection, which may allow the entry of a carcinogen into regulated areas, non-regulated areas, or the external environment.

(10) "Nonregulated area" is any area under the control of the employer which is not subject to the provisions of this section because there is no potential for exposure to a carcinogen.

(11) "External environment" is any environment external to the regulated and non-regulated areas.

(12) "Redundant protection" is a backup system for operations involving carcinogens which is capable of providing immediate protection should the primary system fail.

(13) "Protective work clothing" is clothing designed to protect the worker against contact with or exposure to carcinogens in the regulated areas.

(14) "Emergency" is an unforeseen circumstance or set of circumstances resulting in the release of a carcinogen which may result in the exposure or contact with the carcinogen as evidenced by its detection either by the most sensitive, feasible sampling and analytical methods available or by other obvious evidence such as physical detection or an indication of equipment failure or impending failure, which emergency calls for immediate action.

(d) *Requirements for areas containing carcinogens.*—A regulated area shall be established by the employer where a carcinogen is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be regulated in accordance with the requirements for the following categories of operations involved:

(1) *Isolated System.*—Where a carcinogen is contained within an isolated system, such as a "glove box", employees and other authorized individuals working with such a system shall be required to wash their hands and arms upon completion of the assigned task and before engaging in other unrelated activities.

(2) *Closed system operation.*—Where a carcinogen is stored in sealed containers, or contained in a closed system, such as fully enclosed process or transfer equipment, including pipes; sample ports or openings, if present, are not in use while a carcinogen is contained within:

(i) Access to the regulated area shall be restricted to only employees who work in that area and other authorized individuals.

(ii) Before entering the regulated area each workday all employees and other authorized individuals shall be provided with and be required to wear new or decontaminated appropriate protective work clothing.

(iii) During the workday, such employees and other authorized individuals shall be required to remove and leave that clothing at the point of exit upon each exit from the regulated area.

(iv) Such employees and other authorized individuals shall be required to wash hands and face upon each exit from the regulated area, close to the point of exit.

(v) Such employees and other authorized individuals shall be required to remove and place all protective work clothing in an appropriate container (for purposes of decontamination or disposal) after last exit of the day from the regulated area.

(vi) Such employees and other authorized individuals shall be required to shower after last daily exit from the regulated area, close to the point of exit.

(3) *Transfer from a closed system, charging or discharging point operations,* or otherwise opening a closed system. In operations involving "laboratory type hoods", or in locations where a carcinogen is contained in an otherwise closed system", but is transferred, charged, or discharged into other normally closed containers:

(i) Access to the regulated area shall be restricted to only employees who work in that area and other authorized individuals.

(ii) Continuous local exhaust ventilation followed by appropriate decontamination and disposal shall be maintained to prevent the dispersion of the carcinogen to regulated areas, non-regulated areas, or the external environment.

(iii) Before entering the regulated area each work day, all employees and other authorized individuals shall be provided with and be required to wear new or decontaminated, appropriate protective work clothing, such as smocks, coveralls or long-sleeved shirts and lower pants.

(iv) Such employees and other authorized individuals shall be required to remove and leave that clothing at the point of exit upon each exit from the regulated area.

(v) Employees and other authorized individuals in the regulated area involved in carcinogen handling operations shall be provided with and be required to wear and use appropriate personal protective equipment adequate to prevent exposure to a carcinogen.

(vi) Such employees and other authorized individuals shall be required to wash hands and face upon each exit from the regulated area, close to the point of exit.

(vii) Such employees and other authorized individuals shall be required to shower after last exit of the day from the regulated area, close to the point of exit.

(viii) Employees and other authorized individuals in the regulated area shall be required to remove and place all protective equipment in an appropriate container at the bead site or charging, discharging or transfer point after work at that site or point.

(4) *Open vessel systems.*—(i) Open vessel system operations, as defined above in paragraph c(9), shall be prohibited.

(5) *Maintenance and Decontamination Activities.*—In decontamination of carcinogen(s), either as a part of clean-up of leaks or spills, maintenance or repair operations on systems or equipment, or where direct contact with a carcinogen could result, each employee or other authorized individual entering that area shall:

(i) Be provided with, and be required to wear, a decontaminated, full, impervious, pressurized, air-supplied suit upon entering that area and while engaged in such operations;

(ii) Be decontaminated before leaving that area and before removing the suit; and

(iii) Be required to shower after removing such suit.

(6) *"Out-of-doors systems".*—No distinction shall be made between out-of-door regulated areas and indoor regulated areas.

(e) *General regulated areas requirements.*—In addition to the regulated types of systems listed in paragraph (d) of this section the following requirements apply to all regulated areas:

(1) Each employer shall establish and maintain a list of employees entering a regulated area. The list shall be made available on request to authorized representatives of the Secretary of Labor and the Secretary of Health, Education, and Welfare.

(2) The employer shall provide all work clothing, protective clothing, equipment, and wash and shower supplies including towels, required by this section.

(3) Any required shower rooms shall be provided in accordance with § 1910.-141. Shower supplies may be introduced into a shower room only through a non-contaminated area.

(4) No food, beverage, drug, or cosmetic shall be permitted within a regulated area.

(5) No smoking or smoking materials, tobacco products, or chewing materials shall be permitted within a regulated area.

(6) Appropriate instructions and signs shall be posted at the entrance to, and exit from, regulated areas to inform employees of the procedures that must be followed in entering and leaving a regulated area.

(7) Any equipment, material, or any other items that are to be taken into or removed from a regulated area by any employees or other authorized individuals shall be taken in or removed from such area in such a manner which does not contaminate outside the regulated area.

(8) When only removal of outer clothing or personal protective equipment is required under paragraph (d) of this section, at point of exit from a regulated area, an employee must be able, upon exit from the regulated area, to enter the change room, remove outer work garments and equipment and leave them in that room in an appropriate container.

(9) When change and shower facilities are required under paragraph (d) of this section at point of exit from a regulated area, they shall be arranged so that upon exit, an employee must be able to enter a separate dirty change room where he can undress completely and leave every item of clothing and equipment in approved containers. All clothing shall be decontaminated before laundering. He must then be able to shower in an adjacent room which he can enter through an entrance designed to prevent the escape of carcinogens from the dirty change room to the shower [illegible] enter a clean change room where his street clothes are in his locker.

(10) When work area garments or protective clothing and equipment are required under paragraph (d) of this section to be worn in a regulated area, a clean change room must be provided so that before entering the regulated area, the employee or other authorized individuals can change into clean work area garments or protective clothing and equipment in an area not containing contaminated or used work clothing or equipment and without passing through such a contaminated area to enter the regulated area. The clean change room shall have individual storage facilities for storage of street clothes and clean protective clothing and equipment.

(11) Continuous general mechanical exhaust ventilation shall be provided in regulated areas, or other positive means provided, so that contaminated air from the regulated area does not flow to non-regulated areas. Local exhaust ventilation may satisfy this requirement. Clean makeup air shall replace air removed.

(12) In emergencies, immediate measures shall be initiated, including all of the following:

(i) Evacuation from potentially affected area as soon as the emergency has been determined.

(ii) The release shall be contained and stopped as expeditiously as possible by duly-trained, authorized, and continually available emergency team operating under the conditions described in (e)(5). The makeup of the team shall be determined by need.

(iii) Medical surveillance shall be instituted for any individuals present in the potentially affected area.

(iv) Normal operations in the area are to be resumed only after effective decontamination.

(v) Safe escape in case of an emergency shall be readily possible by satisfactory means of egress.

(vi) Specific emergency procedures shall be prescribed, the terms of such procedures shall be posted, and the employees shall be familiarized with their terms and rehearsed in their application.

(vii) The emergency first aid procedures that shall be used shall be specifically appropriate to the hazard for each carcinogen and these procedures shall be generally recognized as effective.

(f) *Signs and labels.*—(1) Entrances to regulated areas shall be prominently posted with legible signs bearing the legend:

CANCER HAZARD AREA

AUTHORIZED PERSONNEL ONLY

For isolated environment operations, the sign shall be posted on or near the structure containing the isolated system.

(2) Equipment, material, and clothing contaminated with a carcinogen shall not be removed from a regulated area, unless it is either decontaminated or sealed in impervious containers bearing the legend:

DANGER

Contaminated with
CANCER HAZARD AGENT

(3) Entrances to every regulated area for operations described in paragraph (d)(5) of this section shall be prominently posted with legible signs bearing the legend:

CANCER HAZARD IN THIS AREA

ALL IMPERVIOUS PRESSURIZED AIR-SUPPLIED SUIT REQUIRED AT ALL TIMES

AUTHORIZED PERSONNEL ONLY

(g) *Decontamination.*—Decontamination processes shall be established and implemented to remove carcinogens from decontamination facility, that are known to be contaminated with a carcinogen.

(h) *Waste disposal.*—Waste disposal methods and processes shall be established and implemented which do not permit carcinogens to be introduced into regulated areas, non-regulated areas or the external environment.

(i) *Performance Standard.*—(1) Whenever a carcinogen is present, no measurable exposure or contact shall be permitted by any route, oral, respiratory, or skin.

(2) For the purpose of this paragraph "present" shall mean manufactured, processed, used, packaged, released, handled, stored, or otherwise present.

(3) For the purpose of this paragraph "measurable" shall mean detectable, by

(i) the most sensitive, feasible, approved reliable methods of environmental and personal monitoring, and

(ii) the most sensitive approved tests for detecting a carcinogen or its metabolites in biological fluids.

(j) *Monitoring.*—To provide information enabling the employer to comply with the requirements of this regulation, personal and environmental sampling procedures and monitors appropriate to each carcinogen or combination of carcinogens and capable of detecting by the most sensitive, feasible methods available, shall be used by employers to detect and provide a record of the presence of any level of carcinogen in regulated areas and non-regulated areas, and to monitor the discharge of carcinogen into the external environment.

NOTE.—It should be an urgent concern of the Department of Labor in conjunction with the National Institute for Occupational Safety and Health and the Environmental Protection Agency to undertake and/or contract for the development of monitors which shall have a sensitivity of at least one part of carcinogen per billion parts of air (v/v), individual analytical results to be produced by such monitors at intervals no greater than 8 hours throughout the working day. Of equally urgent concern should be the development of backup detection methods capable of producing a warning or signal at intervals no greater than ten minutes, with a sensitivity of at least 100 parts per billion. Methods of equivalent detection shall be developed for water and other wastes. These achievements shall be viewed as milestones along the pathway to achieve the objective of zero exposure rather than as ultimate targets.

(k) *Medical.*—(1) *Surveillance.*—(i) The employer, at his cost shall provide and make available to all employees by a company designated physician, or by another duly-qualified physician of their choice, a comprehensive history and physical examination consisting of diagnostic tests and periodicity specific to the carcinogen and in no less detail than guidelines set forth by the Secretary of the Department of Labor after consultation with the Secretary of Health, Education, and Welfare.

(2) *Records.*—(i) The physician(s) charged with the implementation of the medical program shall maintain the appropriate records. If the employee has been examined by a company-designated physician, a copy of the results of that examination shall be forwarded to the company-designated physician and these records shall be treated in a confidential manner.

(ii) Only physicians and medical consultants of the Department of Labor, physicians designated by the company, and physicians designated and authorized by the employee shall have access to the medical records, where confidentiality of these documents shall be preserved.

(iii) Medical records shall be maintained for the duration of the employee's employment; a copy of these records shall be maintained by the company-designated physician; and in addition, at the termination of employment, the records shall be forwarded by registered mail to the Director of the National Institute for Occupational Safety and Health.

(iv) In the event that an employer ceases business without a successor, medical records shall be forwarded by registered mail to the Director of the National Institute for Occupational Safety and Health.

(l) *Labeling.*—All containers of carcinogens for use other than process equipment shall be labeled prominently with the words:

CANCER—HAZARD

DANGER—AVOID ALL CONTACT AND EXPOSURE

For opening and use by authorized personnel. The chemical and common name shall be clearly identified.

(m) *Training and indoctrination.*—(1) All employees who may periodically or routinely enter a regulated area, including maintenance and supervisory personnel, where any carcinogen is manufactured, processed, used, repackaged, released, handled or stored, shall be provided with an indoctrination program which shall include definitive information concerning:

(i) The nature of the hazards, including local and systemic toxicity, of any of the carcinogens or other potentially hazardous chemicals present in the regulated area,

(ii) The specific nature of the operation or procedure, such as manufacturing, processing, use, repackaging, releasing, handling or storing, which could result in exposure to employees to any of the carcinogens.

(iii) The purpose for and application of a medical surveillance program.

(iv) The purpose for and application of an air monitoring program, and basic understanding of the significance of the various monitoring values.

(v) The purpose for and application of decontamination practices and procedures.

(vi) The purpose for and significance of emergency practices and procedures including bimonthly emergency drill procedures.

(vii) The employee's specific role in emergency procedures.

(viii) Specific information to aid the employee in the recognition and evaluation of conditions and situations which may result in the release of a carcinogen into a regulated area, non-regulated area, or the external environment.

(ix) The purpose for and applications of specific first aid procedures and practices.

first indoctrination program and annually thereafter.

(xi) Assurance by the employer that the employee has a firm understanding of the purpose and applications of the basic information required above.

(xii) Specific training material for workers and supervisors shall be made available through the Office of the Assistant Secretary of Labor for Occupational Safety and Health or the Director of the National Institute for Occupational Safety and Health.

(xiii) The employer shall maintain a record of the administered indoctrination program.

(n) *Reporting.*—Every employer subject to this section shall report in writing to the Occupational Safety and Health Administration, Office of Standards, the following information:

(1) The address of each of his regulated areas;

(2) The name and other identifying information as to the particular carcinogens present in each of his regulated areas;

(3) The approximate number of employees entering each of his regulated areas during a representative week of normal operations in the regulated areas; and

(4) The manner in which the carcinogens are present in each of his regulated areas, e.g., whether a carcinogen is manufactured, processed, used, repackaged, released, or otherwise handled.

(o) *Permit for the Use of Carcinogens.*—A use permit system shall be initiated as an integral part of the permanent standard to provide for effective regulation of conditions and practices concerning carcinogens to enhance the implementation of the standard.

[FR Doc.73-16869 Filed 8-9-73;8:45 am]

DCPA/1ml

American Chemical Society

DEPARTMENT OF CHEMISTRY
AND PUBLIC AFFAIRS

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4600

April 1, 1974
120-03LA-74

MEMORANDUM

TO: Mr. H. H. Fawcett

FROM: S. T. Quigley

SUBJ: Referral to Council Committee on Chemical Safety from the Joint Board-Council Committee on Environmental Improvement

REF: (a) STQ memo to the Committee on Environmental Improvement, #120-02LA-74 of 3/29/74

In the discussion of Reference (a) by the Committee on Environmental Improvement in Executive Session on Sunday, March 31, 1974, the Committee

> VOTED to review, in the context of technical, environmental and economic considerations, the past and potential Society initiatives in developing official ACS policy relative to the substantive and procedural aspects of setting standards.
>
> In pursuit of this objective, the Committee on Environmental Improvement VOTED to seek the opinion of the Council Committee on Chemical Safety.

It is requested that the Committee on Chemical Safety review the published standards on carcinogens and the forthcoming proposed emergency temporary standard on vinyl chloride. The Committee on Environmental Improvement would appreciate receiving the views of the Committee on Chemical Safety at the Committee's earliest convenience.

Thank you for your cooperation.

S. T. Quigley

Enclosure

cc: Dr. R. W. Cairns
Dr. R. L. Kenyon
Dr. T. E. Larson
Mr. H. A. Morrell
Dr. C. G. Overberger

American Chemical Society

DEPARTMENT OF CHEMISTRY
AND PUBLIC AFFAIRS

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4000

1504

March 29, 1974
120-02LA-74

MEMORANDUM

TO: Members, ACS Committee on Environmental Improvement

FROM: Dr. Stephen T. Quigley

SUBJ: Proposed OSHA Emergency Temporary Standard on Vinyl Chloride

The Occupational Safety and Health Administration in the Department of Labor is expected to issue a proposed revised emergency temporary standard on vinyl chloride in light of several reports of fatalities and a study implicating vinyl chloride as a cause of angiosarcoma of the liver.

The proposed rules should be published before April 5, 1974 in the Federal Register. The emergency standard will lower the ceiling exposure for vinyl chloride from the current level of 500 p.p.m. to 50 p.p.m. The "permanent" standard is expected to set 1 p.p.m. as the ceiling for exposure. Most polyvinyl chloride plants are believed to operate their polymerization sections (where the recent fatal exposures have occurred) at exposures of about 50 p.p.m., although recently some plants claim to operate at a level of 10 p.p.m.

To date, at least 11 cases of liver cancer have been linked to vinyl chloride exposure. Vinyl chloride is known to cause other liver diseases and changes in circulation and bone structure in fingers and toes. Polyvinyl chloride is suspected of causing lung damage. A 1961 study shows that a level of 500 p.p.m. of vinyl chloride causes cancer in animals. A recent study by Professor Cesare Maltoni, supported by a consortium of European firms, reveals that liver angiosarcoma found in fatal deaths of vinyl chloride - polyvinyl chloride workers can be induced in rats by exposure to vinyl chloride. B. F. Goodrich Co., the parent company of B. F. Goodrich Chemical Co., has announced that it is funding a medical research program on angiosarcoma at the University of Louisville.

A brief chronology of the events leading to the issuance of a revised standard on vinyl chloride is as follows:

- January 1974: Announcement of an investigation into the cancer deaths of three workers at a B. F. Goodrich Chemical Co. plant in Louisville, Ky.

- February 1974: Administrative rulemaking hearings held by the Department of Labor; Industry witnesses supported a revised standard on vinyl chloride exposure, not as an emergency temporary standard, but through ordinary rule-making procedures; Labor representatives and university scientists supported the emergency standard.

  The Kentucky Occupational Safety and Health Board added vinyl chloride to a list of cancer-causing agents.

- March 1974: The National Institute of Occupational Safety and Health developed recommendations on analytical methods for detection of vinyl chloride under plant conditions. OSHA announced that an emergency standard would be issued by early April 1974. B.F. Goodrich Co. announced funding for a medical research program on angiosarcoma and related liver diseases.

Does the committee wish to review the emergency temporary standard on vinyl chloride and develop a draft ACS policy statement for presentation at a rulemaking hearing?

S. T. Quigley

cc: Dr. R. W. Cairns
Mr. H. H. Fawcett
Dr. R. L. Kenyon
Mr. H. A. Merrill
Dr. C. G. Overberger

AMERICAN CHEMICAL SOCIETY

COMMITTEE ON CHEMICAL SAFETY

1508

Attendance

A.C.S. Meeting on Vinyl Chloride

Marvel Hall - 21 May 1974

Name	Mailing Address
Dr. Victor Brum	VA Center, Medical Research Lab 15-A, Togus, Maine 04330
Dr. Zeb Bell	A.I.H.A., PPG Industries, 1 Gateway Center, Pittsburgh, PA 15222
Ms. Joan Broom	NAS-NRC, 2101 Constitution Ave., N.W. Washington, D.C. 20418
Mr. Howard Fawcett	NAS-NRC, 2101 Constitution Ave., N.W. Washington, D.C. 20418
Dr. Herman Kraybill	National Cancer Institute, National Institutes of Health, Bethesda, MD 200
Dr. Donald Lassiter	OSHA, 1726 M St., N.W., Room 620, Washington, D.C. 20210
Dr. Nina McClelland	National Sanitation Foundation, P.O. Box 1468, Ann Arbor, Michigan
Dr. Bernard McNamara	Edgewood Arsenal, SAREA-CL, Aberdeen Proving Ground, MD 21010
Mr. Halley Merrell	A.C.S., 1155 16th Street, Washington, D.C 20036
Dr. Glenn Schweitzer	EPA, Office of Water Programs, Division o Oil and Water Hazardous Materials, 401 M St., S.W., Room 1113 E, Washington, D.C. 20460
Dr. F.A. Van Atta	Office of Standards, Department of Labor, 1726 M St., N.W., Room 410, Washington, D.C. 20210 Stop #205
Dr. Elizabeth Weisberger	National Cancer Institute, National Institutes of Health, Bethesda, MD 200
Mr. George White	NAS-NRC, 2101 Constitution Ave., N.W. Washington, D.C. 20418
Mr. George Wilson	ASTM, E-34, Firestone, Akron, Ohio

ENCLOSURE NO. IV

AMERICAN CHEMICAL SOCIETY

COMMITTEE ON CHEMICAL SAFETY

1597

23 May 1974

MEMORANDUM

To: Attendees at ad hoc Panel on Vinyl Chloride, May 21, 1974
Members, Committee on Chemical Safety

Subject: Proposed ACS Comments on Vinyl Chloride Regulation
(Federal Register, Vol. 39, No. 92, May 10, 1974,
Pages 16896-16900)

Please note the attached draft of the proposed statement by the Society on the vinyl chloride regulation. I have taken the liberty of editing this to a minor degree but am hopeful this contains your thoughts and opinions.

Due to the extreme urgency of time, we ask you to telephone any comments (either positive or negative) directly to the American Chemical Society so appropriate action can be taken as soon as possible. Specifically, if you will call Dr. Nathan J. Karch on telephone number 202-872-4466 or 4467, or Dr. Halley Morrell on 872-4610 (202) by noon Tuesday, May 28, we would greatly appreciate it. We would of course welcome any comments in writing, but recognizing the urgency of time, we must ask you please to telephone your comments to Dr. Karch or Mr. Morrell.

Your continuing cooperation in this matter will be greatly appreciated by the ACS, by Dr. Victor Bruni who chaired the meeting, and by myself.

Sincerely yours,

H. H. FAWCETT
Chairman
Committee on Chemical Safety

HHF:rj

Enclosure

RECEIVED
MAY 24 1974
REG. DEPT.

The American Chemical Society has a strong interest and recognizes its responsibilities to both the public and the private sectors concerning both the benefits and potential hazards from chemicals and their uses. For these reasons, we have noted and carefully reviewed the most recent information on the subject of vinyl chloride in occupation exposures and its relationship to sarcomas.

Angiosarcoma is a rare carcinogenic lesion in the general population. The appearance of angiosarcoma in occupationally exposed groups, much higher than in the general population, shows a casual relationship for an occupational vector. There is enough data to characterize vinyl chloride as a carcinogen--a potent hepatocarcinogen. There is sufficient data to indicate that this is a carcinogen for other sites, i.e., kidney, bone. Epidemiologically, this should be sought for beyond liver. Survey reports now show extrahepatic angiosarcoma.

Referring to Federal Register, May 10, 1974, pages 16896-16900, Vol. 39, No. 92 [29 CFR Part 1010], (f)i), it is suggested a grace period of reasonable but limited duration be extended for industry to meet these standards considering engineering design and their economic effects, with feasible controls to be instituted as soon as possible.

Regarding limits of exposure, the following quotation, extracted from page 11 of the report, CHEMICALS AND HEALTH, Report of the Panel on Chemical and Health of the President's Science Advisory Committee (National Science Foundation) September 1973, chaired by Professor John W. Tukey, appears germane to the subject:

> "A 'no-detectable amount' clause is a refuge in the face of ignorance. Were mature scientific knowledge presently available regarding dose-response relationships and extrapolation to man, the problem of carcinogenicity could be dealt with a scientifically rational manner. We have good reason to believe--though it is not yet proved--that some, perhaps most, chemical carcinogens will have definable thresholds."

Vinyl chloride has an apparent threshold and a definable dose response curve.

Regarding (g) and (h), we endorse the control methods outlined but suggest further consideration to the possible air-supplied suits fabricated from material impervious to the expected exposure. The air supplied for breathing must be as good as or better than that required by CFR 1910.134.

Consideration should be given by NIOSH/B of M for an approval schedule commensurate with specific needs for protective equipment for vinyl chloride and polyvinyl chloride exposures and appropriate maintenance and decontamination procedures for such equipment.

We strongly endorse the concept that transporters or disposers of any chemical, including vinyl chloride, should be properly informed of the potential hazards and adequately trained in the safety precautions to be observed.

The American Chemical Society continues to encourage the rapid and wide dissemination of information and data on the potential hazards of chemicals, and will continue to provide a forum for such purposes on all chemicals and chemically-related substances.

ENCLOSURE NO. V4510

American Chemical Society

MEMBERSHIP
ACTIVITIES DEPARTMENT

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4000

June 12, 1974

MEMORANDUM

TO: Members, ACS Committee on Chemical Safety
Members, ad hoc Task Force on Vinyl Chloride Standards

FROM: Halley A. Morrell, Staff Liaison
ACS Committee on Chemical Safety

SUBJECT: Draft ACS Statement on Vinyl Chloride Standards

As you know the Committee on Chemical Safety (CCS) was asked by the ACS Committee on Environmental Improvement at the ACS National Meeting in Los Angeles to review the proposed OSHA Standard for Employee Exposure to Vinyl Chloride.

On May 23 Mr. Fawcett submitted to you for review and comment a draft of the proposed ACS statement on the proposed vinyl chloride standard. Based on your comments and further input Mr. Fawcett prepared a revised version of the draft and this was submitted to the ACS Department of Chemistry and Public Affairs for further review prior to submittal to the ACS Committees on Environmental Improvement and on Chemistry and Public Affairs.

I am enclosing a copy of the draft submitted to the Committees on Environmental Improvement and on Chemistry and Public Affairs for their comments and recommendations prior to its submittal to the ACS Board of Directors for approval.

It would likely be helpful if the ad hoc task force and CCS members were on record as recommending Board approval of the statement. If you approve the statement, may I request that you telephone me immediately (202-872-4610).

Thank you.

Halley Morrell

HAM:dl
Enclosure

RECEIVED
JUN 13 1974

American Chemical Society

DEPARTMENT OF CHEMISTRY
AND PUBLIC AFFAIRS

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4600

W.A. Mensell JUN 10 1974

June 7, 1974
120-368-74

MEMORANDUM

TO: Members, ACS Committee on Environmental Improvement
Members and Consultants, ACS Committee on Chemistry and Public Affairs

FROM: Dr. Stephen T. Quigley

SUBJ: Draft ACS Policy Statement on the OSHA Standard for Employee Exposure to Vinyl Chloride

Enclosed you will find a copy of the subject draft statement for your review. A deadline of 5:00 p.m., Wednesday, June 12, 1974 for receipt of your comments and recommendations by telephone (202/ 872-4474 or 4466) is necessary to allow sufficient time for the review and approval of the draft statement by the ACS Board of Directors.

The recommendations of the Committee on Chemical Safety (CCS) have been incorporated into the enclosed draft statement. The recommendations of CCS were developed in response to the following action taken at the March 1974 executive session of the Committee on Environmental Improvement (CEI):

> VOTED to review, in the context of technical, environmental and economic considerations, the past and potential Society initiatives in developing official ACS policy relative to the substantive and procedural aspects of setting standards.
>
> In pursuit of this objective, the Committee on Environmental Improvement VOTED to seek the opinion of the Council Committee on Chemical Safety.

It was requested that CCS review the standard on vinyl chloride. Shortly after my memorandum (120-93LA-74) on behalf of CEI referred this matter to CCS, an *ad hoc* panel of experts on vinyl chloride was convened by Mr. H. H. Fawcett, Chairman of CCS, and chaired by Dr. V. C. Brum on May 21, 1974 to develop recommendations and comments on the proposed standard. The CEI Subcommittee to Develop a Model Protocol in Setting Regulatory Standards also has been reviewing the proposed standard on vinyl chloride.

For your convenience, I have enclosed copies of the proposed standard from the Federal Register of May 10, 1974 and the announcement of a rulemaking hearing from the Federal Register of May 24, 1974. You will note that the deadline for submission of written comments is June 10, 1974 and that a request for an opportunity to appear at the June 25, 1974 rulemaking hearing must be submitted by June 17, 1974. Clearly, the Society will be unable to meet the June 10, 1974 deadline for submitting written comments. Thus, a request to appear at the June 25, 1974 rulemaking hearing will be submitted on June 17, 1974.

I look forward to your comments and suggestions.

S. T. Quigley Jr.

Enclosures (3)

cc: Dr. H. S. Bloch
Dr. V. C. Brum
Dr. R. W. Cairns
Mr. H. H. Fawcett
Dr. D. S. Friedman
Dr. R. L. Kenyon
Mr. H. A. Merrell

DRAFT NO. III 6/4/74

STATEMENT

of

THE AMERICAN CHEMICAL SOCIETY
to the
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
UNITED STATES DEPARTMENT OF LABOR

on the

PROPOSED VINYL CHLORIDE OCCUPATIONAL EXPOSURE STANDARD

[29 CFR Part 1910.93q]

June 25, 1974

The American Chemical Society appreciates the opportunity to submit comments and recommendations regarding the Occupational Safety and Health Administration's Proposed Vinyl Chloride Occupational Exposure Standard.

The Society's Committee on Chemical Safety, whose membership includes persons with recognized expertise in chemical safety matters from universities, industry, labor, government, and the medical field, has long been concerned with the physical safety and well-being of practicing chemists, engineers, and persons working with hazardous and potentially hazardous material. In its consideration of the proposed vinyl chloride standard, the Committee on Chemical Safety has also consulted with scientific experts outside the membership of the Society to broaden the Society's perspective on this issue.

The recommendations of the Committee on Chemical Safety have been reviewed by two additional Society Committees -- the Committee on Environmental Improvement and the Committee on Chemistry and Public Affairs -- before being reviewed and approved by the ACS Board of Directors. We believe the views presented here by the American Chemical Society represent a consensus of the chemical science community.

It is appropriate that the American Chemical Society present this statement since it has a National Charter which imposes obligations on the Society to provide assistance to the government in matters of national concern related to the Society's areas of competence and also to work for the advancement, in the broadest and most liberal manner, of chemistry, "thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

Founded in 1876, the American Chemical Society was chartered as a non-profit, scientific and educational organization by an act of Congress which was signed into law on August 25, 1937. Current membership in the Society is about 110,000 individual chemists and chemical engineers. The Society has no corporate memberships. The membership reflects a broad spectrum of engagement in academic, governmental, and industrial professional pursuits. About 60% of our members are employed by industry, about 25% by academic institutions, and 15% by government and non-profit institutions.

Chemicals, in a wide variety of forms, constitute the basis for all life. Approximately 4.5 million chemicals have been isolated and identified. Thousands of these chemicals are safely manufactured, transported and used in large quantities. Thousands more are used in smaller quantities for very limited and specific purposes over a wide spectrum of human endeavors, frequently by the public. Often a chemical will posses one or more properties which present a hazard to human health or safety, such as corrosivity, toxicity, explodibility, flammability, or carcinogenicity. However, carcinogenicity is unique among the hazards of chemicals because the amount required to induce effects in generally not known, and there usually is a long induction period between exposure and effect.

The American Chemical Society has noted and carefully reviewed the most recent information [1-6] on the subject of vinyl chloride and polyvinyl chloride with residual monomer in occupational exposures and the suspected relationship of vinyl chloride to angiosarcomas in humans. Angiosarcoma is a rare carcinogenic lesion in the general population. Vinyl chloride has been found to induce angiosarcomas of the liver in mice at exposure levels as low as 50 p.p.m. and as low as 250 p.p.m. in rats. This information on experimental animals, when considered in relation to the discovery of the same rare angiosarcomas of the liver in humans who had been exposed to vinyl chloride, strongly suggests a causal relation between vinyl chloride exposure and the appearance of the angiosarcomas in humans. There also appears to be indications that vinyl chloride is a carcinogen for sites other than liver [3,6] and the Society recommends that epidemiological studies to confirm these preliminary findings be undertaken.

What remains in question, however, is the actual level of exposure to vinyl chloride which may induce angiosarcomas in humans. The Society recognizes that there is no scientific data currently available to conclusively set a threshold limit for safe exposure of humans to vinyl chloride. Some chemical carcinogens have indeed been found to have an apparent threshold value.

Thus, in the absence of data establishing a safe level of exposure to vinyl chloride and in the interests of public health and welfare, the Society endorses the proposed standard for the level of employee exposure. [1] However, the American Chemical Society recommends that a reasonable period of time be given employers to allow for detailed engineering design and development of equipment necessary for compliance.

The Society endorses the control methods outlined in sections (g) and (h) of the standard, but suggests that consideration also be given to requiring

workers to wear air-supplied suits fabricated from materials impervious to vinyl chloride. In the Society's view, an approval schedule should be developed that is commensurate with specific needs for protective equipment against exposure to vinyl chloride and polyvinyl chloride with residual monomer. Appropriate maintenance and decontamination standards and procedures should be made available for such equipment.

The Society views the provisions of section (l)(6) and section (n) of the standard regarding exhaust ventilation as addressing only the problem of employee exposure. A local exhaust ventilation system which assists in reducing the concentration of vinyl chloride below the detectable level may help provide sufficient safeguards for an employee in the immediate vicinity, but increased reliance on ventilation methods does not have any impact on the problem of the potential hazard from ambient levels of vinyl chloride. A preliminary survey by the Environmental Protection Agency 7/ indicates the presence of ambient levels of vinyl chloride under present plant operating conditions that are in excess of the proposed exposure level in the standard.

The American Chemical Society notes with much interest the provision that transporters, handlers, disposers, and others exposed incidentally must be properly informed of the potential hazards and must be adequately trained in the safety precautions to be observed. We emphasize that adequate labeling must be maintained at all times if this objective is to be achieved. A clear definition of the word "vessel" in this context should be included in section (b) of the standard.

The Society has long encouraged and supported the rapid and wide dissemination of information on the potential hazards of chemicals. As an example, the ACS Committee on Chemical Safety has scheduled a symposium on chemical carcinogens, including vinyl chloride, for the ACS National Meeting in Atlantic City, New Jersey in September 1974.

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In summary, the American Chemical Society recognizes the potential threat to an employee exposed to vinyl chloride or polyvinyl chloride with residual monomer and endorses the proposed standard for occupational exposure. The Society believes that the control methods outlined in the standard are feasible, but again urges that provision be included for a reasonable grace period for compliance with the standard. The Society offers these suggestions to the Occupational Safety and Health Administration in a spirit of cooperation in the hope of developing the best possible mechanism for balancing the potential hazards and benefits of vinyl chloride.

Attachment: References

References:

1. Federal Register, 39 (92), 16896-16900 (1974).

2. C. Maltoni, et al., Record of a fact-finding hearing on possible hazards involved with the manufacture and use of vinyl chloride, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, D.C. (February 15, 1974).

3. P. L. Viola, "Cancerogenic Effect of Vinyl Chloride," Abstr. 10th International Cancer Congress, Houston, Texas (May 22-29, 1970), p.20; P. L. Viola, A. Bigotti; A. Caputo, "Oncongenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride," Cancer Research, 31, 516-522 (1971).

4. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois, under contract to the Manufacturing Chemists Association, Washington, D.C. Press Release, MCA-3839 (April 15, 1974).

5. Tabershaw/Cooper Associates, Inc., Berkeley, California, under contract to the Manufacturing Chemists Association, "Epidemiological Study of Vinyl Chloride Workers," Final Report (May 3, 1974).

6. Office of the Scientific Coordinator for Environmental Carcinogenesis, Division of Cancer Cure and Prevention, National Cancer Institute, National Institute of Health, U.S. Department of Health, Education and Welfare, "Vinyl Chloride Exposure and Neoplastic and Non-Neoplastic Disease," transcript of the 9th meeting of the Interagency Collaborative Group on Environmental Carcinogenesis (April 17, 1974).

7. A survey of approximately one-third of vinyl chloride and polyvinyl chloride plants indicates ambient levels of vinyl chloride, and the Environmental Protection Agency has requested data on losses into the air to consider whether to issue an emission standard. EPA Press Release, No. R-471 (May 31, 1974); and a pending press release on the results of the survey scheduled for distribution by Friday, June 14, 1974.

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August 19, 1974

Mr. John Stender, Assistant Secretary
Department of Labor
Room 3115
14th & Constitution Ave., N.W.
Washington, D.C. 20210

Dear Mr. Stender:

I was a member of the American Chemical Society (ACS) ad hoc task force on vinyl chloride which met at ACS headquarters in Washington, D.C. on May 21, 1974. I represented the American Society for Testing and Materials (ASTM), Committee E-34. Subsequently, a first draft of the ACS proposed statement was circulated to me.

A third draft of the ACS proposed statement was received on June 14, 1974. Mr. P. D. Halley, Chairman of the ASTM E-34 Committee, instructed me to phone ACS on June 14, 1974, and to state that ASTM could not endorse the third draft statement which ACS proposed to give at the public hearings on vinyl chloride. I did so on June 14, 1974.

I am told that during cross-examination after ACS gave their statement at the public hearings on vinyl chloride, an ACS spokesman indicated there were two members on the task force who represented the vinyl industry. The fact is, I represented only ASTM as a member of the ACS task force. In no way did I represent The Firestone Tire & Rubber Company, nor did the statement given by ACS reflect the views of The Firestone Tire & Rubber Company.

Very truly yours,

George L. Wilson,
Corporate Industrial Hygienist

cc- Dr. L. H. Ballou

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UNION CARBIDE CORPORATION
CHEMICALS AND PLASTICS
P. O. BOX 8361, SOUTH CHARLESTON, W. VA. 25303

August 22, 1974

Mr. Julius Jimeno
Hearings Management Officer
Docket OS H-36
Room 200
Occupational Safety and Health Administration
U.S. Dept. of Labor
1226 M Street, N.W.
Washington, D.C. 20210

Dear Mr. Jimeno:

As a member of the American Chemical Society for the past 20 years, I would like to add my objection to the position taken by the executive board of ACS relating to the proposed permanent standard for vinyl chloride.

Firstly, the position does not reflect my position nor that of the majority of my member associates.

Secondly, the board acted independently without canvassing the membership and without appraising the local sections of their intended action.

Thirdly, the proposal submitted at the Public Hearings in Washington, D.C., did not have the approval of all the ACS board members. In fact, one of the industry representatives was not given the opportunity to review the final position of the Society before it was presented.

The available medical facts, in my estimation, do not support the extreme position taken by the ACS board. Furthermore, the achievement of "no detectable vinyl chloride" is impossible in any practical commercial operation which the board would have realized had it solicited comments from the many industry members of the Society.

Thus, the ACS position advanced at the Hearing should be considered the personal opinion of selected members of the board and not the majority view of the membership of the Society.

Very truly yours,

J. John Brezinski

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July 3, 1974

IPD JUL 8 1974

11-C

Dr. Louis Belicky
Division of Industrial Hygiene
UNNIU
87 South High Street
Akron, Ohio 44308

Dear Dr. Belicky:

Enclosed is a preliminary draft of our work with low doses of vinyl chloride in fish. We have since been able to reproduce the skin lesions at 20 ppm for two weeks.

Very truly yours,

William C. Dolowy, D.V.M.
Professor of Microbiology

WCD:ms

cc: Mr. Angelo Cefalo
International Association of
Machinists and Aerospace Workers

P.S. I enclose a gross slide of one of these fish for each of your use next week.

Preliminary Draft

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TOXICITY OF VINYL CHLORIDE IN NORTHERN PIKE (ESOX LUCIUS)

I P D JUL 8 1974

William C. Dolowy,[1] Eric R. Brown,[1] James J. Hazdra,[2] Stephen Greenberg[3] and Parker Beamer[3] and Steven O. Schwartz [4].

Supported in part by EPA contract R-802087, FDA contract 73-201, Blood Research Inc., Evelyn Steinberg Memorial Foundation, Leukemia Research Foundation, Joel Elowe Memorial Foundation, Orrin Kurzband Memorial Foundation and the American Blood Research Society.

1) Department of Microbiology, University of Health Sciences/The Chicago Medical School, Chicago, Ill. 60612
2) Department of Chemistry, Illinois Benedictine College, Lisle, Ill.
3) Department of Pathology, University of Health Sciences/The Chicago Medical School, Chicago, Ill. 60612
4) Department of Medicine, Northwestern University Medical School, Chicago, Ill.

Hepatomas have been previously produced in various fish by a variety of chemicals. Aflatoxin produces hepatomas in trout (1,2) and guppies (3). Dimethylnitrosamine produces hepatomas in trout (4), the zebra danio (5) and guppies (3). Two-acetylaminofluorene also produces hepatomas in guppies (3).

Vinyl chloride was reported to have caused angiosarcomas in the liver of humans employed in plastic plants while exposed to this gas. Fifty ppm in the air is now regarded as unsafe.

We wished to ascertain whether vinyl chloride was carcinogenic to Esox lucius and, if so, the latent period between exposure and tumor production and the relation between vinyl chloride concentration and time from tumor induction to death.

Methods

Esox lucius were kept in tanks of five fish each and exposed to doses of up to 388 to 400 ppm vinyl chloride (Table I). The gas was bubbled through the water to form a saturated solution. Various control tanks of fish were included, one tank with dechlorinated tap water, six tanks of five fish each with distilled water, and 20 fish were placed in a small lake, (Illinois Benedictine Lake), as controls. Fish were fed live minnows once a week. The fish ranged from 6 to 19 inches in length. The tanks varied from 10 to 20 gallons in size. The water was continuously filtered through Dyno-flo filters with filter floss. The filter floss was changed every three days, and the water was changed every two weeks.

Results

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Table I shows the acute rapidity with which vinyl chloride killed fish in the 388 ppm concentration. The appearance of a tumor in the distilled water and dechlorinated tap water groups, though the fish at a later time than in the vinyl chloride group, was perplexing until we discovered that a graduate student had used a single net to clean large pieces of uneaten minnows from all three tanks daily.

Analyses of water for vinyl chloride in a second experiment to estimate the contamination with vinyl chloride transferred by the net indicated that a range of 20 to 45 ppm of vinyl chloride was present in the distilled water and dechlorinated tap water tanks. All these analysis were performed by a Perkin Elmer Model 900 gas chromatograph using a flame ionization Detector, 4% carbowax-KOH 750 on chromasorb G packing, 2 feet long programed from 60-120°C.

The low incidence of deaths in the control fish in the lake, one of 20 in 73 days, substantiates that the effects were due to a material in the tanks, rather than a peculiarity of this whole shipment of fish.

The lesions were first visible grossly by the loss of scales, followed by the appearance of swelling in the lateral sides of the fish. Histologic sections of the liver were examined by two pathologists (Dr. S. Greenberg and Dr. P. Beamer).

Microscopic appearance of the skin lesion include loss of scales, the underlying muscle necrotic with infiltration of cells between skin and muscle and between muscle bundles. These cells are as yet of unknown origin, but are mononuclear and some eosinophilic cytoplasm. Some of these cells are also present

The gross hepatic lesion is shown in Figure I. Microscopic examination of liver sections from different animals show consistant findings. Portions of the liver are occupied by one or more circumscribed, non-encapsulated masses or cords of cells containing abundant pale cytoplasm, large nuclei and prominent nucleoli. The nuclear chromatin has an irregualr, sometimes peripheral, arrangement. There are occassional abnormal mytotic figures. Scanty connective tissue stroma supports most of the cells. There are scattered dense connective tissue areas in the sections. A medium size vessel (hepatic arterial branch) was observed to contain luminal masses of cells similar to those in the lesion.

The tumor proved to be a hepatoma with areas of necrosis, in contrast to the agniosarcoma found in humans.

The liver lesion also differs from the trout hepatoma induced by aflatoxin in the lack of fibrous connective tissue in the liver of pike exposed to vinyl chloride while connective tissue is a rather prominent feature in the trout hepatoma.

Conclusion

The toxic and possible hepatocarcinogenic effects of vinyl chloride are very rapid (under 70 days); the concentration of vinyl chloride in water needed to produce a hepatoma appears to be very low (4.5 to 20 ppm); the northern pike may be susceptible to the production of hepatomas by vinyl chloride. Previous shaker

TABLE I

TOXICITY OF VINYL CHLORIDE IN NORTHERN PIKE (ESOX LUCIUS)

Treatment	No. Fish	No. Fish Dead	No. of Days Post Vinyl Chloride	Actual Vinyl Chloride Count PPM
Vinyl chloride 388 ppm	5	5	10	383
"Distilled water"	30	25	36	20
"Dechlorinated tap water"	5	5	44	4.5
Illinois Benedictine Lake	20	1	120	-

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REFERENCES

1. Kraybill, H.F. and Shimkin, M.B. Carcinogenesis Related to Foods Contaminted by Processing and Fungal Metabolites. Adv. Cancer Res., 8:191-248, 1964.

2. Halner, J.E.; In Aflatoxin (Goldbentt, L.A., Ed.). New York Academic Press, 1969, pp. 265-306.

3. Sato, S., et al. Hepatic Tumors in the Guppy (Lebistes reticulatus) Induced by Aflatoxin B_1 Dimethylnitrosamine and 2-Acetylaminofluorene. Jour. Natl. Cancer Inst. 50:765-778, 1973.

4. Ashley, L.M. and Halver, J.E. Dimethylnitrosamine-Induced Hepatic Cell Carcinoma in Rainbow Trout. Jour. Natl. Cancer Inst. 41:531-552, 1968.

5. Stanton, M.F. Diethylnitrosamine-Induced Hepatic Degeneration and Neoplasia in the Aquarium Fish, Brochydanio rerio. Jour. Natl. Cancer Inst. 34:117-130, 1965.

6. Rucker, R.R., Yasutake, W.T. and Wolf, H. Trout Hepatoma PRELIMINARY REPORT

1328

July 19, 1974

IPD JUL 8 1974

Dr. Herman Kraybill
Science Coordinator
Environmental Carcinogenesis
National Cancer Institute
Landlow Boulevard A-321
Bethesda, Maryland 20014

Dear Dr. Kraybill:

We enclose the preliminary draft of the proposed contract concerning the effects of vinyl chloride on northern pike which we discussed by telephone this week.

We would be pleased to receive any of your suggestions for improving the proposal and will be happy to submit a completed proposal if you believe the project is meritorious.

Very truly yours,

Eric R. Brown, Ph.D., V.M.Sc.
Professor and Chairman

ERB:ms
Enclosure

AN UNSOLICITED REQUEST FOR CONTRACT FUNDS TO STUDY THE TOXIC AND CARCINOGENIC EFFECTS OF VINYL CHLORIDE IN FISH

by

William C. Dolowy and Eric R. Brown

BACKGROUND

Vinyl chloride has been reported to cause angiosarcomas in the livers of personnel working in plastic plants. Skin lesions and a hepatoma in northern pike have been found in young pike exposed to vinyl chloride (Reference 1 enclosed). The acute skin lesions in fish are visible after a brief constant exposure of 20 ppm in the surrounding water for as short a period as two weeks.

We found nine hepatomas in fish in the Elgin area, a heavy industrial site. Dr. Nancy Beech indicated to us that levels of 2 ppm of vinyl chloride were found in other industrial sites, therefore, we have an interest in working at levels of vinyl chloride at the 2.2 to 5 ppm level.

PURPOSE

The objectives of the proposal are to ascertain the toxic effects of both the single short term administration of vinyl chloride which might simulate an acute industrial, railroad, or ship spill at one extreme, and the effects of long term exposure at moderate to low levels of vinyl chloride in northern pike, *Esox lucius*.

PLAN

Esox lucius 9 to 12 inches long will be purchased from Peterson Trout Farm, Peterson, Minnesota.

These fish will be exposed to vinyl chloride for the duration of the experiment and at the concentrations listed in Table 1. They will be observed by a laboratory assistant daily. One of the scientist's on the project will examine the fish every Monday, Wednesday and Friday for signs of loss of scales, external lesions, lethargy, CNS disturbance, and the fish will be weighed for size comparison with the control animals. The controls will be kept under identical conditions except without vinyl chloride.

Gross necropsies will be performed on all fish which die spontaneously. Histopathologic examination will be performed by board certified pathologists (PDB and SG) who are also trained in animal pathology, and serial sections of all fish will be undertaken.

Because of our previous pilot findings, special attention shall be paid to examination of the liver, kidneys and skin. Even when the liver may appear normal by gross examination, it may be in early stages of hepatomas and we will attempt to detect these early malignant lesions.

In addition to histopathology, a number of other laboratory tests shall be performed as a monthly or bimonthly; hematology, (RBC, WBC, DIFF, Hb), parasitology, etc.

RESULTS

We will determine the LD's as noted: The LD_{10}, LD_{50} and LD_{99} shall be determined for each duration of exposure in accordance with Table 1. A replicate experiment will be carried out for each dose level of vinyl chloride.

Toxicity:

The hematology, pathology and clinical signs will be studied by killing one fish every 60 days after the beginning of exposure. This will be done for each of these determinations, except that sick or moribund fish will be immediately sacrificed and examined.

SUMMARY

We feel that the toxic or carcinogenic effects of vinyl chloride can be effectively recognized in this animal system. By netting, the effects of levels in the river system (Fox River), we can also note the natural incidence of tumor produced by this agent in nature.

BUDGET

	1st year	(Est.) 2nd year
Salaries:		
Dolowy, William C.* (50%)	$15,000	$15,000
Histologist (100%)	7,000	7,000
Technician (50%)	5,000	5,000
Fringe Benefits: *Professional (10.2%)	1,530	1,530
Non-Professional (9.0%)	1,080	1,080
Equipment:		
6 Exposure Tanks @ approx. $1,200/ea.	7,200	7,200
4 Holding Tanks (Need six, two on hand) @ approx. $600/ea.	2,400	2,400
Supplies:		
Fish - 600 *Esox lucius* and Transportation	750	750
Vinyl Chloride and Pumps	1,000	1,000
Charcoal Filters, Syringes, Miscellaneous	500	500
Histopathology Supplies:		
3,000 Slides @ $1/ea.	3,000	3,000
Microtome @ $500/ea.	500	500
Water Bath, Stains, Etc.	500	500
Embedding Equipment	2,000	2,000
Overhead:		
At 72.10% of Salaries and Fringe Benefits	21,610	21,610
TOTAL:	$69,090	$69,090

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and part (3) on the third paragraph, part (9), you suggested the medical records should be kept for the workers' lifetime.

Do you mean all workers, no matter what the life of their exposure to vinyl chloride?

MR. MAZZOCCHI: Precisely. There is no evidence that we can accept that associates time with carcinoma.

I think I have not seen any evidence that there are thresholds that we would accept.

I mean there is a debate within the scientific community on this subject, and when any scientist debates over such an inportant concept as that, we would gravitate to the most prudent cause.

In our experience the prudent thing would be, would be to demonstrate that people with very short term exposures can cevelop it later on.

MR. KUCHENBECKER: I have some questions for the actual vinyl chloride workers.

Have you, on occasion, used respirators during your employment?

MR. JENSEN: Some of the people in our plant have, but there is a recent development subsequent to the Goodrich situation in vinyl chloride with exposure to vinyl chloride I am speaking of, and other operating situations so yes, they have used them in the past.

MR. KUCHENBECKER: Would you be willing to wear

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respirators for a period up to several years in order for the industry to get down to the level OSHA sets?

MR. JENSEN: I think the people would out of necessity, do so, with reluctance, and probably some necessary procedures built in to provide for relief.

Some of these people have breathing difficulties aready from the chemical exposure, and other people even a normal healthy person would have difficulty breathing over a long period of time with a respirator, particul-rly an effective one.

MR. KUCHENBECKER: How about the gentleman on the far left?

MR. BEC[illegible] Yes.

MR. KUCHENBECKER: Do you care to respond to those two questions?

MR. BECK: I have never worn a respirator myself. I don't work in the PVC plants. I work in the emulstion plant, but I do work with vinyl chloride, producing vinyl chloride type of emulsion, but we do have the respirators. They have not been issued yet, but we have them.

Every man will have one, and every man tells me he will wear it.

In the PVC plant they are wearing them now. It is not a strict order that they wear them, but they do have them in their possession, and I understand they do wear them at

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times when it is most difficult, but they do wear them.

MR. KUCHENBECKER: Thank you.

MR. KLINE: I have just a few questions.

Letuus talk about the Goodyear plant for a moment.

In your view, why would the fact that they can reach a level of eight parts per million mean that they can reach a non-detectable level?

MR. MAZZOCCHI: They just started this procedure to arrest the exposure. They haven't reached operating procedure at the present moment.

There is certainly no doubt in our minds that they can reach the non-detectable level with appropriate controls. They are on their way.

The people who work in the facility tell us that they are on their way, and I gather the company has also indicated there are certainly more to be done.

It is only a few months since this whole procedure has been put into effect.

MR. KLINE: Now, are you aware of the length of time it takes to receive equipment that is ordered in order to reduce levels of exposure?

MR. MAZZACCHI: We are in no position of knowing in every single instance.

I would imagine it is very old, depending upon a whole host of factors that I would be unaware of at the present

w-19

moment.

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Sure, here would be periods of time, if we again speak to the situation on a variance procedure where it can be demonstrated that one could not get down to that level based on all the factors that we contribute to not getting down to the level, even if it was the inability to not secure a piece of equipment.

Certainly, that would be a legitimate request on the part of the employer.

MR. KLINE: Do you know whether there are any PVC companies that could meet the level of non-detectable level by October of 1974?

MR. MAZZOCCHI: It is our impression that a great proportion of them probably could.

We have not done a systematci study. We are dealing with large industry, for the most part.

We are not dealing with the type of employer like the one who testified here before us.

We are not dealing with the American-world chemical industry, and we are quite aware of their ability to meet certain deadlines when they have to meet them, and if they can't, they are very candid in telling us they can't, and then it is up to them to introduce the proof that they can't.

We are not holding to an iron-fast rule that someone is going to create something out of nothing.

hws-20

We recognize the problem, and we recognize there have to be inducements, pressures, rather than inducements.

There have been sufficient numbers of inducement. We feel pressure is absolutely necessary.

MR. KLINE: Now, would it be fair to say that your opinion of industry is trying to con OSHA in terms of technical feasibility?

MR. MAZZOCCHI: Well, characterize it any way you want.

I think it is the natural thrust of industry to get by with as much as they can. It is to their purpose, and if they can delay the date, certainly our experience with them, they will travel the road of least resistance, and it is not because they are bad guys there, and we are good guys here. It is the nature of institutions.

MR. KLINE: Would it be fair you just base that on your general experience?

MR. MAZZOCCHI: Yes, a long experience. A similar question such as vinyl chloride.

In other areas we are very confident of their ability to meet this particular deadline. They have demonstrated their abilities countless times in the past.

There may be some that can't. We ought to take those up on an individual basis.

We are not prepared to characterize everyone as

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being in the same boat. 1533

MR. KLINE: Do you have any industry that you think has been trying to con us?

MR. MAZZOCCHI: The evidence in Goodyear. Our Goodyear testimony shows us that the SPI testimony is an attempt, if you wish to use the word con, are attempting by saying we can't do it by a particular time, and it is too expensive, and not feasible.

We are saying the Goodyear testimony certainly demonstrates that in an atiquated facility, that they were able to get down rather rapidly considering the time span from discovery of the problem to their acting on it.

MR. WODKA: In other words, you have a plan that is meeting a deadline that SPI says the industry cannot meet until 1976, and I think that is a crucial point, that you set a standard to protect people, and that forces people under the pressure to meet that standard like Goodyear, if Goodyear wasn't then under the gun to come down to a non-detectable level by 1974, you wouldn't have seen the massive kind of effort they were doing.

MR. KLINE: Would it be your view that in only a few PVC companies could meet a non-detectable level, that those companies should be required to do so, and that the remainder of them should be required to use the variance procedure?

MR. MAZZOCCHI: We are suggesting any company that

MR. WODKA: Right, which we indicated in our testimony, that there were excursions.

Again, we are talking about averages, just as you talked about averages in your testimony.

MR. HECKMAN: Of course. That is the only point I am trying to establish, is that you were talking about an average.

MR. WODKA: That is correct.

MR. HECKMAN: And I think that is all I need to ask.

JUDGE MYATT: Mr. Connolly?

MR. CONNOLLY: I am Walter B. Connolly, Jr., Firestone Corporation.

Mr. Mazzocchi, you indicated at the outset of your testimony, that you embraced the testimony of President Bommarito on behalf of the United Rubber Workers.

MR. MAZZOCCHI: That is right.

MR. CONNOLLY: Do you embrace everything Mr. Bommarito said in his testimony?

MR. MAZZOCCHI: We embrace everything he said.

MR. CONNOLLY: Do you embrace the statement by Mr. Bommarito at page 180 of the transcript that pursuant to the rigorous cross examination of Mr. Kline:

"Mr. Kline: The recommendation that one part per million be set as the --- or that no-detectable level be

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set?

"Mr. Bommarito: Well, I don't think you can put it in immediately. I think there are a number of things that the companies ought to be given an opportunity to correct."

Do you embrace that particular statement?

MR. MAZZOCCHI: My assistant tells me he later corected himself.

Would you read us the corrected statement?

MR. CONNOLLY: I don't believe he corrected it at all.

MR. WODKA: He later corrected himself as to what the questioner was driving at.

MR. CONNOLLY: I think it was Mr. Beliczky who said something later on.

MR. MAZZOCCHI: Read it off again, and I will tell you whether or not I do.

MR. CONNOLLY: "The recommendation that one part per million be set as the -- or that no-detectable level be set?"

That was Mr. Kline.

"I don't think you can put it in immediately. I think there are a number of things the companies ought to be given opportunity to correct."

MR. MAZZOCCHI: We stand on our statement. If Mr. Bommarito feels that way, we certainly don't feel that way.

MR. CONNOLLY: So you do not embrace Mr. Bommarito.

MR. MAZZOCCHI: We embrace his statement.

MR. CONNOLLY: Has your organization undertaken any economic, technological or engineering studies to determin the feasibility of getting to the no-detectable limit?

MR. MAZZOCCHI: No, we are not in any position to do that.

MR. CONNOLLY: You indicated that you had the impression that companies could reach the no-detecable limit by October of 1974.

What did you base that impression on?

MR. MAZZOCCHI: This is the usual method we use, an empirical method.

We talk to the people who work in the facilities. We talk to them about their experience with the particular companies like Goodyear, and we measure to see whether these things are feasible.

This is a tried and true method.

MR. CONNOLLY: Can you indicate the names of the people that you talked to, that the companies can get to the no-detectable level by 1974?

MR. MAZZACCHI: Well, we can indicate a few of the groups.

Goodyear certainly is one.

MR. CONNOLLY: Who at Goodyear did you talk to

that said that?

MR. MAZZOCCHI: Our Goodyear local union. 1542

MR. CONNOLLY: Who in the Goodyear local union?

MR. MAZZOCCHI: It would be officers of the local union.

MR. CONNOLLY: Are any of the officers engineers or chemists?

MR. MAZZOCCHI: No.

MR. CONNOLLY: What did they base their determination on?

MR. MAZZOCCHI: Their determination was based on the fact that the company has gone from levels that they have never measured, that we have reasons, based on our own experience, to the levels that were very high, to the levels that Mr. Wodka just read.

MR. CONNOLLY: That is all you based it on?

MR. MAZZOCCHI: That is fairly substantial, the evidence that shows the readings have gotten down to the 11 parts per million average.

MR. CONNOLLY: Do you understand the difference between average and time weighted average?

MR. MAZZOCCHI: Yes.

MR. CONNOLLY: And we have 95 percent of the jobs where I say one to five parts per million, and five percent of the jobs were at 25 to 50 parts per million, would not the

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average probably be very close to ten parts per million?

MR. MAZZOCCHI: That is conceivable.

MR. CONNOLLY: How do you propose to get the five percent of the jobs down to the lowest detectable limit by October, 1974, or ever?

MR. MAZZOCCHI: We don't know whether your example represents the facts as they exist in particular industrial facilities.

Again, in talking to our people --

MR. CONNOLLY: Excuse me --

JUDGE MYATT: Let him finish.

MR. MAZZOCCHI: Based on our discussions with the people, we have taken these averages, and what we have suggested here is that the feasibility of getting it down to 11 ppm is based on their observations and their consultations with the company.

We talked about the excursions.

We talked about the fact that when excursions occurred the local unions addressed themselves to the problem, especially at Goodyear, and managment convinced them that their proposed engineering changes would get those excursions down.

MR. CONNOLLY: Are you saying then that you don't know how many, what percentage of the jobs were in excess of ten parts per million?

MR. MAZZOCCHI: I would have to ask. 1584

Are you aware of that based on the monitoring data?

MR. WODKA: We can figure that out.

MR. CONNOLLY: Your testimony is based on not knowing that data?

MR. WODKA: I would have to figure out which ones. Do you want a percentage figure? I don't have it right now.

MR. CONNOLLY: What I am trying to understand is the five percent or ten percent of the jobs, or two percent of the jobs, whatever the figure is, that is in excess of ten parts per million that is included in the total picture at least to an average of somewhere around ten.

I am trying to understand from you how you are going to get that ten percent, or five percent, or one percent of the jobs below ten percent by 1974.

MR. WODKA: We indicated in our testimony that the wide and persuasive amount of jobs in that plant are at an average of ten or below except, and we indicated this when I was cross examined by the Solicitor's Department, when it came to reactor cleaning, the evidence in the Goodyear plant shows that the reactor cleaning is above ten and below 50, averages in between there, and it is our position that reactor cleaning will never be a non-detectable exposure level job; that it should be an air supplied space suit kind of job.

MR. CONNOLLY: So that reactor cleaning jobs then,

you would not be asking the Department of Labor to reduce that to the lowest detectable level.

MR. WODKA: I think we were dealing in the realm of reality here, that those operations will never come down to that, and just because they can't come down to a non-detectable level, gives the industry no excuse to excuse the rest of the plant.

MR. CONNOLLY: In the realm of reality are you referring to it as not technological or engineering feasible to get the lowest detectable level in certain jobs, i.e., what you are saying?

MR. WODKA: I am talking completely within the realm of feasibility on all accounts, economic, technological, engineering.

MR. CONNOLLY: But certain jobs you indicated cannot be gotten down.

MR. MAZZOCCHI: Let me read a letter dated July 2 from one of our representatives:

"With the enclosed readings you will notice that the ppm's are coming down and, in fact, most of them are well below ten ppm.

"I think our problem is going to be reactor cleaning in the bagging stations.

"I also woner what is being discussed concerning the dust in the airborne particles.

"The company is in the process of trying to bring the dust down with ventilation. A lot can and has to be done. When a man is covered with PVC he stands and blow his clothing off with an air hose releasing a dust cloud in the surrounding area.

"Any (inaudible) lines are blown free in the air which has PISC of 80, and is breathed into the atmosphere of the working place.

"Steve, don't let the industry try to tell you a bunch of crap, because I worked in a poly plant with those low readings.

"All that is needed is a concerted effort dealing with the engineering technology, and the goal can be reached."

MR. CONNOLLY: Now, I appreciate your reading that self-serving letter into the record.

MR. MAZZOCCHI: This is a worker in a plant.

JUDGE MYATT: Ask your next question.

MR. CONNOLLY: Relating specifically to the plant, there are engineering controls that are available to get to the lowest detectable limit.

Will you indicate for the record what those engineering controls are?

MR. MAZZOCCHI: I can't do this at the present moment.

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We will be happy to consult with the local unions at Niagara Falls and submit that for the record.

What we base our position here on is a conduit for expressing the concern of our members, and it is not for the dotting of the "i's" and the crossing of the "t's." We will do that.

We will take the model as established up at that plant and submit it in toto for the record.

MR. CONNOLLY: I am trying to understand, though, from my own standpoint, and the standpoint of the Department of Labor, you indicated a number of companies can get to the lowest detectable limit by utilizing various engineering controls between now and October, 1974, and you are telling me no you don't know what the engineering studies are.

MR. MAZZOCCHI: It is a fair question, and we will submit in detail the narrative and the chronology of the experience at Goodyear in Niagara Falls.

I think it is a good suggestion.

MR. WODKA: I also think the point is this. We are dealing with possibly the worst, if not one of the worst plants in the company in terms of past exposure, age 1946, in terms of small reactors, a totally closed facility, and I personally have been through that plant, and I know it is an old plant.

MR. CONNOLLY: How many plants have you been

through?

MR. WODKA: PVC plants?

MR. CONNOLLY: Yes.

MR. WODKA: Polymer plants?

MR. CONNOLLY: Yes.

MR. WODKA: Just one.

MR. CONNOLLY: How do you know it is the worst in the industry?

MR. WODKA: Well, again, I am basing it on what I have seen, what I have heard here from testimony, and again, there is the extent of disease in this plant, that Dr. Selikoff has testified to and yet, all this put together in the last few months, this company has come down to ten parts per million and below.

MR. MAZZOCCHI: We know you fellows talk to each other a great deal, and you ought to know.

MR. CONNOLLY: You indicated in your testimony that better engineering controls will cut down chronic exposure.

Now, I take it there is a dichotomy between cutting down and fully eliminating it.

Now, are you indicating that just some engineering controls in other areas, other than reactor cleaning, can only cut down the exposure levels as distinguished from reducing them to the lowest detectable limit?

MR. MAZZACCHI: That is expression.

Certainly, the first phase of any reduction program would be to cut down.

The second stage in any time sequence would be to eliminate, and the point we make in that part of the testimony, as you well know, industry thrust has been to cut manpower to the bone, and to neglect maintenance, and some total neglect of this procedure is what we are dealing with here today.

We are saying if we revert to what we used to do in maintaining a plant the way it should be maintained, we would probably get back to the lowest exposure level.

MR. CONNOLLY: You are saying if it is a two-step phase, one is cutting down, and the ultimate getting to the no-detectable.

MR. WODKA: We are saying in certain situation if you say to a fellow that the pump is leaking, or that piece of equipment is leaking, would you take initial steps to correct it, and to come back and eliminate the emission.

Yes, there are sometimes time sequences based on a particular set of problems in that site that might take a day.

MR. CONNOLLY: It might take a year.

MR. WODKA: If it takes a year, one would have to demonstrate that it takes a year.

MR. CONNOLLY: So then you would be embracing

Mr. Bommarito's statement in response to Mr. Kline's question.

MR. WODKA: Again, I go back to my own statement saying where the burden ofproof should be on the industry there should be a deadline.

If there is a legitimate reason why you can't meet that deadline, then you ought to come forward.

We can't conceive of every particular set of circumstances in every particular plant in the United States.

There may be a situation, and it may be in a plant that you are at, or you are speaking for. It may be. We do not know.

Our experience demonstrates that we think, and based on what we have said, they can meet it.

The exceptions, there are remedies. It is another part of the Act.

MR. CONNOLLY: Are you saying then, that I presume you are saying, that there are some jobs that cannot be rescued to the lowest detectable level, and in those jobs every company in the country that is in this industry will have to come in and request a variance.

MR. WODKA: We think certain jobs you will never reduce it, reactor cleaning.

MR. CONNOLLY: So that every company in October would have to come in and ask for a variance.

MR. WODKA: The way we conceive of it, and I have

to check the standard, the proposed standard again, but the standard would be written in such a way that where it is technologically not feasible, for example, reactor cleaning, to bring it down to a non-detectable level, then that environment becomes a space suit air-supplied respirator kind of job, and there would be no need for the companies to come in for a variance, because that would be indicated in the standard.

MR. CONNOLLY: Now, as Mr. Kline, I believe it was, asked you, is it your feeling that if equipment is not available to reduce the level for the companies in other areas, other reactor cleaning between now and October of 1974, and that equipment was one or two years away, that every company would be coming in in October requesting variance, and abatement periods would be set up?

MR. MAZZICCHI: We hope the companies approach the problem with candor, and based on the problems of the realities of the situation.

If they have a problem, they use that part of the Act that allows them to use the variance procedure.

At that time, the onus would be on them to demonstrate they can't do certain things at a certain time.

We taken them up point by point. These would not be blanket exceptions.

MR. CONNOLLY: When you suggest that different companies might be in obviously different situations, are you

suggesting that a different standard might be appropriate for different types of companies?

MR. MAZZOCCHI: No, we are not. We are saying again the Act addresses itself to that point, allows a variance.

It gives them a period of time to come into compliance.

It allows intra-measures, and we say where a company can legitimately demonstrate that it needs the variance, and can provide equal protection as called for under the Act, then we would take that up on an individual basis.

MR. WODKA: In other words, we propose that all of our members throughout the three parts of the vinyl chloride industry be covered by a non-detectable exposure limit.

MR. CONNOLLY: You indicated, Mr. Mazzocchi, that industry in the asbestos case came in and indicated that it was not economically and technologically and engineering feasible to get down to low levels, and this has not proven to be the case.

Is it not a fact that the number of companies have been unable to reduce the asbestos exposure to the acceptable limits at this juncture?

MR. MAZZOCCHI: We have an experience in doing a poll showing that companies that made no effort whatsoever to attempt to meet the standard, yes, less than one percent in our industry, less than three percent in our industry, less

It is just my impression, because at one time in the operation people used to pile the stuff, and had to carry it some distance, and put it on a calendar, and those people were probably exposed to a pretty good measure of vinyl chloride.

Again, absent any real objective indication, it is my impression that they were over a long period of time.

MR. MAZZOCCHI: Let me point out one other point in regard to your question.

No one counted prior to the episode at Goodrich for the most part, except Dow, and maybe one or two others, that we have been able to determine, and that seems to be the history of most contaminants.

You don't measure anything until somebody comes up and says there is a problem.

The SPI in the Solid Waste Act of 1970 made a point about all this nonsense of PVC contamination when they were addressing themselves to PVC, and solid waste said there is no harmful effects of PVC.

By the way, I am sure that PSI knew at that time that Dr. Maltoni had shown that there was a problem developing.

MR. CONNOLLY: Is this 1970?

MR. MAZZOCCHI: 1970. Just go back to the record.

MR. CONNOLLY: One last question.

How many readings were taken at the Goodyear plant on each individual employee, and over what period of time?

MR. WODKA: Let's see. There was 32 per shift, and they were taken on all three shifts, so that would be what, 96 a day.

MR. CONNOLLY: Thirty two readings per employee?

MR. WODKA: No, 32 throughout the plant per shift, plus reactor cleanings were separate.

MR. CONNOLLY: You tell me there were 32 readings taken at 32 different spots around the plant for each shift.

MR. WODKA: Each shift.

MR. CONNOLLY: And those were the only readings taken?

MR. WODKA: These were the only readings that were submitted to the local union.

MR. CONNOLLY: No further questions.

Thank you.

JUDGE MYATT: Any further questions?

MR. BARR: I am John t. Barr from Air Products and Chemicals.

I have a few questions, and I would like to start with Mr. Deck.

I believe you started working in the emulsion plant. You worked the polyvinyl chloride plant also.

MR. DECK: No, sir, I did not.

MR. BARR: Just in the emulsion plant?

MR. BECK: No, sir, I worked in the catalytic

1430	15	Insert "for those companied" after "mechanism"
1430	22	Change "gove." to "go."
1432	9	Change "particul-rly" to "particularly"
1433	24	Change "is very old." to "a variable"
1438	4	Change "become" to "count the"
1445	14	Change "ten" to "two"
1447	6	Change "(inaudible) to "plug "
1447	7	Change "PISG" to "PSIG"
1450	11	Change "lowest" to "no".
1451	17	Change "rescud" to "reduced"
1452	22	Change "taken" to "take".
1456	2	Change "pile" to "mill"
1456	19	Change "PSI" to "SPI"
1457	17	Change "t." to "T."
1458	5	Change "started" to "used to argue"
1459	5	Change "bee" to "been"
1460	21	Delete "angio-"
1460	22	Change"OSHA" to "NIOSH"
1463	4	Change "ans" to "and"
1502	6	Insert "medical" before "evidence"
1502	7	Change "low" to "below 50 ppm."
1502	10	Change "exposure." to "production."
1502	11	Change "acquire" to "require"
1506	16	Change "?" to"with excursions to 40 ppm?"
1510	22	Change "new technical" to "no detectable"

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SUMMARY OF TESTIMONY BY
UNIROYAL, INC.
IN OBJECTION TO THE PROPOSED
PERMANENT STANDARD 1910.93q
RELATING TO VINYL CHLORIDE EXPOSURE

DOCKET OSH-36

June 21, 1974

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SUMMARY OF TESTIMONY BY UNIROYAL, INC. IN OBJECTION TO THE PROPOSED PERMANENT STANDARD 1910.93q RELATING TO VINYL CHLORIDE EXPOSURE

I am Martin J. Kleinfeld, Commercial Planning Director of the Chemical Division of Uniroyal, Inc. I am a chemist and for nine years, from 1948 through 1956, I was involved in research and development and manufacturing of vinyl chloride and polyvinyl chloride resins. In subsequent years I have been successively Marketing Manager and Research and Development Manager for Uniroyal's PVC resin operations.

My associates are Dr. Walter Harris, Corporate Toxicologist; Mr. Benton Leach, Factory Manager of our Painesville, Ohio polyvinyl chloride manufacturing facility and Mr. Richard Weller of Arthur, Dry & Kalish, our legal firm.

Uniroyal has been in the business of manufacturing vinyl chloride monomer and polyvinyl chloride resins for 27 years. We are one of the world's major manufacturers of vinyl products such as coated fabrics (under the trade name of Naugahyde) and have been for 33 years.

While we were the third producer of polyvinyl chloride in the U.S. we have not expanded as rapidly as some and currently account for only about 3 percent of the total U.S. production. It is noteworthy, however, that with only 3 percent of the total production and about 300 people directly involved in the manufacture of these resins we affect about 25,000 employees in customers' fabricating operations dependent at least in part upon our resins. A simplified extrapolation of this ratio for the industry would suggest that as many as 800,000 employees could be adversely affected by a major cut-off of the polyvinyl chloride supply; and this does not, of course, account for the hundreds of thousands of

(CONTINUED)

workers whose jobs would be affected by a stoppage in the flow of fabricated products which are dependent upon polyvinyl chloride and not amenable to near future substitution of other materials, many of which are also in short supply as a result of the energy shortage.

As mentioned, our plant at Painesville, Ohio has been in continuous commercial operation for 27 years. During the first 14 years of operation we also produced vinyl chloride monomer at the same site. During these 27 years we have produced over 1.5 billion lbs. of PVC and have employed about 800 people in this plant during this period. 150 of these have worked in close proximity to the VCM/PVC operation for over 16 years; 56 of these for over 25 years. The medical data we have accumulated to date have disclosed no incidence of angiosarcoma and the incidence of abnormal liver function test results appears to be no greater than in the general population.

We are submitting to the OSHA at this time our written detailed discussion of our objections to the Proposed Standard; 19 are enumerated in our submittal. In the interests of conserving time I will highlight now only those points which we believe are of greatest importance relative to safety considerations and the economic impact of the Proposed Standard.

A. Objections to Specific Portions of Proposed Standard

1) Our major objection is to the "no detectable level" restriction. This has been detailed in our EXHIBITS A-1, A-2, A-3, A-7, A-9 and A-17 following.

2) We do not see the need for special protective clothing as we are unaware of any evidence that has proven a medical risk due to skin absorption of vinyl chloride gas. (See EXHIBIT A-6)

3) We believe the respiratory section should be written with more flexibility to allow the use of a greater variety of respirators based upon their proven ability to cope with the situation at hand. (See EXHIBIT A-11)

(CONTINUED)

4) "Emergency" situation by definition should be confined to release of large quantities of vinyl chloride. (See EXHIBIT A-4)

5) The mandatory requirement for removal of personnel from potential vinyl chloride contact areas if upon medical rescreening one or more abnormal liver function tests persist, leaves the examining physician no room for judgement. Furthermore, removal of an employee to an area with "no detectable level" of vinyl chloride, which in our opinion, is unlikely to be found consistently in the vicinity of a vinyl chloride or polyvinyl chloride plant, would appear to leave no alternative but transfer or dismissal. (See EXHIBIT A-16)

B. Technological Nonfeasibility

Regulations involving protection of workers and their health must recognize the fact that absolute safety in any work situation is impossible. From a technical point of view steps can be taken to reduce risk to a minimum.

At our PVC production facility it is not feasible to reduce airborne concentrations of vinyl chloride to zero. The attached report from our consulting engineers, Bowshot, Cooper and O'Donnell supports this contention. (See EXHIBIT B)

It is feasible to reduce exposure to vinyl chloride to a low level but not to a non-detectable level. At our plant we have initiated engineering changes and improved work practices to minimize worker exposure to vinyl chloride. A major change being planned involves automatic vessel cleaning which requires an investment, in our relatively small operation, of over $1 million. Improved ventilation in general will also improve the working atmosphere.

19571 ROSELAND AVE.
CLEVELAND, OHIO 44117
PHONE 692-0460

Bowshot, Cooper & O'Donnell

ENGINEERS

H. L. COOPER 16570
J. F. O'DONNELL 16732
R. K. FIELD 24278
R. E. SCHAEFFER 25065

June 14, 1974

Uniroyal, Inc.
P.O. Box 460
Painesville, Ohio 44077

Attention: Mr. W. M. Iliff
Plant Engineer

Subject: To reduce the concentration of Vinyl Chloride Monomer in the working areas of your Painesville Plant to a level of one part per million (1PPM)

Dear Sir:

Our study has indicated that from an engineering standpoint, reducing the concentration to this level is impractical to the point of being impossible. In reaching this conclusion we gave careful consideration to the following factors.

1. The "state of the art" at the present time does not permit the measurement of 1PPM of VCM in your area. All of the methods used for detecting VCM to some extent either respond to other hydrocarbons or are reduced in sensitivity by their presence. The use of alcohols and acetates etc. around and in the Uniroyal Plant plus marsh gas and automobile contaminants serve to produce a variable "background" that would make calibration of any continuously monitoring instrument almost impossible to a level of one part in a million of VCM only.

   During our investigation of this problem we have examined most of the instruments used to measure the quantity of VCM present.

   All these instruments have had a poor history for serviceability. It is unlikely that immediate improvements will be made to increase their reliability beyond what is now being experienced.

19571 ROSELAND AVE.
CLEVELAND, OHIO 44117
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Bowshot, Cooper & O'Donnell

ENGINEERS

H. L. COOPER 16570
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R. K. FIELD 24378
R. E. SCHAEFFER 23065

Uniroyal, Inc.

June 14, 1974

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2. Due to the batch process of making PVC, some VCM must be lost during cleaning and recharging of the vessels.

3. The polymerization or conversion of the monomer is less than 100% so that even with current stripping technology some of the monomer is included in the final product. Some monomer will be discharged from resin drying systems as well as in the finished product.

4. VCM must be stored, transported, and pumped at a pressure greater than atmospheric. The most assiduous maintenace program will not prevent some leaks.

5. Vinyl Chloride Monomer is a volatile explosive gas at normal ambient conditions and relatively low concentrations. The only safe method to eliminate the explosive danger after it has been exposed to air is dilution by ventilation.

6. The amount of ventilation required to approach 1PPM would result in air speeds through the buildings that would cause excessive noise, unsafe working conditions, and unacceptable structural changes to the walls for explosion release. The heat required to temper this volume of air would be an impractical waste of energy.

7. It is our opinion that the most practical way to significantly reduce VCM levels in a PVC resin plant is through the application of known engineering principles in the design of an entirely new facility. To bring a plant built within the last ten years to such a standard appears to be impractical.

Very truly yours,

BOWSHOT, COOPER & O'DONNELL
ENGINEERS

James F. O'Donnell
Partner & Chief Engineer

Howard L. Cooper
Partner

C. PVC Processing and Fabrication

We do not believe that the proposed Standard should be written to cover PVC processing workplaces. There is no evidence of medical hazard in these operations. Although it is possible to detect some VCM in the processing workplaces it is unusual to find any substantial concentrations. Proper workplace ventilation and emphasis on reducing residual VCM levels in PVC should insure the absence of risk.

Data on monitoring of processing workplaces within Uniroyal may be found in EXHIBIT C.

Although we reject the concept of "zero exposure" to vinyl chloride, we recognize - and accept - our responsibility to protect the health of our workers. We believe that low level exposure to vinyl chloride represents a minimal risk situation. We recommend that a finite "permitted level" be substituted in the Permanent Standard in place of the "no detectable" requirement.

In our PVC manufacturing operation we feel that we can reduce airborne levels of vinyl chloride to under 50 ppm as a ceiling limitation. For practical purposes we strongly endorse the concept of a TWA value. In our opinion the TWA number could ultimately be set at 25 ppm and the ceiling at 40 ppm if it is felt that sufficient evidence exists to warrant reduction from 50 ppm called for in the Temporary Standard.

It should be recognized that due to individual plant design and operation, compliance dates should be on a plant to plant basis. We urge that OSHA personnel - with outside engineering consultants if necessary - establish a proper and achievable timetable for regulatory compliance at each plant location.

Regarding the future, we do not believe that permissible vinyl chloride exposure levels should be set lower and lower unless there is more adequate medical justification. Proper epidemiological studies should be immediately initiated to evaluate the degree of risk at low levels of vinyl chloride exposure.

D. Economic Impact

Another major objection to the concept of "no detectable" restrictions on vinyl chloride involves the economic impact which would result from the closing of production plants due to the technological infeasibility of meeting such a Standard.

The Department of Labor recognizes the validity of economic impact arguments in the prologue to carcinogen regulations issued as Part 1910's c-p (FR, Vol. 39, No. 20 - January 29, 1974). They state ... "the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable, consistent with continued use". The prologue also exempts or excludes certain operations or levels of alleged carcinogens on the basis that without such exclusions or exemptions the Standards ... "would have the effect of closing down large segments of industry, such as steelmaking, wood preserving, roofing, aluminum reduction, and possibly even power plants".

The polyvinyl chloride (PVC) industry is the single most important segment of the entire U.S. plastics industry. Annual output of base resin is close to 5 billion pounds per year. A recent survey by Peter Sherwood Associates (Chemical Marketing Reporter - 5-27-74) projects growth to 8.5 billion pounds in 1980.

It should be recognized that the growth of PVC to this tremendous usage stemmed from the unique properties of this resin. Uses and fabricating techniques have for the most part been developed to handle PVC and are not easily adapted, or adapted at all, to other materials. One does not simply substitute rubber or another plastic without substantial changes in skills, equipment and capital costs.

A rough breakdown of application areas follows. (Chemical Marketing Reporter - 5-20-74)

	PVC Use Areas
Pipe and Fitting	27%
Flooring	10
Construction	6
Wire and Cable	9
Furniture	6
Transportation	5
Film and Sheet	4
Textile, Paper and Adhesives	5
Sound Records	3
Export	5
Miscellaneous	20

The total worth of the PVC industry in terms of jobs and dollars is difficult to measure exactly but it is known to be responsible for hundreds of thousands of jobs and many billions of dollars. Other presentations at this hearing will give additional data on the magnitude and importance of the PVC industry.

To grasp the proliferation of impact starting with our Chemical Division PVC production facility, we have made a rough economic analysis based on predicted effects on Uniroyal as well as our customers. It has been noted that although we are a small producer of PVC (about 3% of the U.S. total) the impact of a shut down of our PVC plant would create severe economic effects.

At our Painesville, Ohio PVC production plant we employ about 300 people with an annual payroll of about $4 million. The resin we produce is used by other Uniroyal divisions and outside customers giving employment to over 25,000 people and an annual payroll of over $200 million.

Communities that would suffer from the loss of PVC - related jobs within the Uniroyal corporation are: Painesville, Ohio; Port Clinton, Ohio; Stoughton, Wisconsin; Philadelphia, Pennsylvania; Mishawaka, Indiana; Chicago, Illinois; Farmville, Virginia, and Washington, Indiana.

Industries that would be severely affected by curtailment of our PVC production operations include: coated fabrics, flooring, footwear, medical, automotive, shoes, hose, insulation, wire and cable.

In EXHIBIT D we have illustrated some detailed effects that would results within the Uniroyal organization.

OR20233

EXHIBIT D
p. 1 of 4

JUN 13 1974 COM. DEV.

UNIROYAL, Inc. 1568

OXFORD D-2-2
(Location)

June 12, 1974

R. J. Dowling
NAUGATUCK CHEMICAL

SUBJECT: PROPOSED VCM OSHA REGULATION #1910.939

The Plastic Products Division would be forced to shut down our Coated Fabrics and certain Royalite ABS-Thermoplastic Sheet operations if the proposed Government standard of "zero" or "no detectable level" of vinyl chloride exposure is made permanent.

This would result in an immediate loss in Divisional sales of over $100 million/yr. At a minimum, 1,812 salary and wage jobs would be eliminated with an annual value of wages and salaries in excess of $18,580,000. (This value is exclusive of Fringe Benefits)

The number of employees effected with monthly wage and salary loss by plant is listed below:

PLANT	WAGE EMPLOYEES	MONTHLY WAGE LOSS	SALARIED EMPLOYEES	MONTHLY SALARY LOSS	SALESMEN
Chicago, Ill.	150	$155,204	30	$ 35,268	4
Stoughton, Wisc.	240	198,663	42	42,116	
Port Clinton, Ohio	250	192,436	65	62,906	
Masland-Phila.,Pa.	350	230,046	90	91,702	12
Mishawaka, Ind.	360	305,712	147	139,240	73

The economic impact on the local communities of Mishawaka, Port Clinton, and Stoughton would be extremely severe since these plants are either the largest or next largest employer in their respective area.

In addition, approximately 122 Coated Fabrics Distributors averaging 10 employees each would be effected as 26% of their business is derived from the sale of vinyl coated fabrics.

R. Morgan
Richard Morgan

j

cc: W. J. Mulvey

INTERCOMPANY CORRESPONDENCE

JUN 7 1974 COM. DEV.

UNIROYAL, Inc.
Consumer Products
Oxford R-1-31 1589
(Location)

June 6, 1974

TO: R. J. Dowling
Naugatuck Chemical Division

FROM: F. C. Cesaro

SUBJECT: Proposed VCM OSHA Regulation #1910.93q
R.I. Consumer Products Co.

The Consumer Products Co. would include the Farmville, VA and Washington, Indiana plants.

In Farmville the economic impact would be as follows if we could no longer operate under the non-detectable OSHA requirements, loss in Net Sales in excess of $6 million.

Salary and wage jobs eliminated 216.

Value of wages and salary in dollars $1,600,000.

The loss of $2,600,000 in materials cost and overhead which includes purchases from local vendors and the community such as taxes, utilities, etc.

At the Washington Indiana plant the loss in net sales would be over $4 million and the elimination of 100 salary and wage positions.

The value of salary and wages is $870,000 and the materials and overhead dollars which would be lost to the community is estimated at $366,000.

Since the Washington Indiana plant manufactures other products it is conceivable that a balanced plant could not exist profitably and that under these conditions the losses could be greater. In the event of total plant shut down the loss in net sales would amount to $12,000,000, the salary and wages lost would be approximately $3,585,000. The materials and overhead dollars lost to the local community and vendors would be $1,355,000. The total number of positions eliminated assuming complete plant close down would be 416.

1570

There are no substitutes for plastisol or slush cast footwear in Farmville, VA or for the clothing operation in Washington, Indiana.

F. C. Cesare

FCC/dh

cc: D. Thomson
P. G. Brown
E. C. VanBuskirk
D. Dudrow

EXHIBIT D
p. 4 of 4

UNIROYAL

UNIROYAL, INC.
Route 2, Box 32
Farmville, Virginia 23901

June 7, 1974

RECEIVED
JUN 12 1974
D. THOMSON
1571

Mr. John Stender
Assistant Secretary of Labor
U. S. Department of Labor
Washington, D. C. 20210

Dear Mr. Stender:

We have been following with some interest the information developing on the Poly Vinyl Chloride problem and have read the proposed rules for emission standards as contained in OSHA Regulation 1910.93Q.

Our plant currently employs some 220 people with an annual payroll in the area of $1,600,000. In addition we are billed from the community for services some $600,000 annually.

The material cost for manufacturing our products approximates $1,600,000.

We are certainly receptive to practical regulations for the protection of personnel both in industry and at the consumer level and encourage such action.

Any regulations set up must be manageable and realistic in order for us to protect the livelihood and health of everyone involved. Any impractical regulations resulting in cutbacks or shutdowns would certainly introduce undue hardship on people employed in our plant and have an adverse effect on the local community.

Any efforts by your department to help insure practical regulatory procedures while also insuring proper health safeguards would be appreciated.

A. C. Young
Factory Manager
Uniroyal, Incorporated
Farmville, Virginia

ACY:sw

2572

I think that the testimony and comments presented at this hearing should have made it clear to all of us who are concerned with the health of people and of the economy that the precipitate action proposed in the Permanent Standard would not be in anyone's best interest.

I believe Dr. Hammond, Vice President of the American Cancer Society, made a very rational statement when he said, as quoted in the news media, "There's no such thing as zero risk; I want to get the risk down as low as feasible, so low that I wouldn't hesitate myself to take that employment. But I don't want to make it so low that I couldn't earn a living...."

We would like to go on record in favor of a practical and reasonable set of controls. We feel in good conscience that a time weighted average of 50 ppm of vinyl chloride in both vinyl chloride monomer plants and polyvinyl chloride plants would be proper protection, supported by the data now available.

We believe that there should be no restriction on polyvinyl chloride processing and fabricating plants so long as the residual vinyl chloride content of the resins used is not over 0.1%.

(CONTINUED)

We do not believe that any schedule of <u>future</u> changes should be written into the initial Standard or should be adopted at this time. Such changes should be instituted only when and if justified by data from a properly designed study. And we think it is extremely important to emphasize that such a study, to be valid, must include proper control groups. Before we jump to the conclusion that angiosarcoma is related only to vinyl chloride, or any other agent for that matter, or that the potential for development of angiosarcoma is increased by any level of exposure, it should be mandatory that we determine first what the incidence of angiosarcoma is in the general population and how it relates to occupational exposure.

LMc 28

the possibility of any significant residual life.

Section (k) regarding signs and labels. The use of the word "cancer" on signs and labels, we believe, creates emotional and irrational fears and morale problems which are not warranted. We believe the use of the word "hazardous" plus action-oriented instructions in place of "cancer-suspect" would accomplish the desired purpose of this section much more effectively.

Also, no label requirements should apply to polyvinyl chloride unless a hazardous situation can reasonably be anticipated based on residual vinyl chloride content.

Section (o), medical surveillance and mandatory removal of personnel from the job. We mentioned before the mandatory requirement for removal of personnel from potential vinyl chloride contact areas if upon medical rescreening one or more abnormal liver function tests persist leaves the examining physician no room for judgment. Furthermore, removal of an employee to an area with "no detectable level" of vinyl chloride, as we mentioned before, is not likely to be found in an operating plant, would appear on the basis of the proposed regulation to leave us no alternative but dismissal or transfer.

We don't think that was meant. We recommend that removal of personnel from a work area be the discretionary responsibility of the examining physician who will be in the best position to take into account all of the employee's

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symptoms and other medical background which can affect such a decision.

Comments on the technological nonfeasibility. Regulations involving protection of workers and their health must recognize the fact that absolute safety in any work situation is impossible. From a technical point of view, steps can be taken to reduce risk to a minimum.

At our PVC production facility it is not feasible to reduce airborne concentrations of vinyl chloride to zero. We are including as one of the exhibits in the submittal a report from our consulting engineers supporting that contention.

It is feasible to reduce exposure to vinyl chloride to a low level but not to a nondetectable level. At our plant we have initiated engineering changes and improved work practices to minimize worker exposure to vinyl chloride. A major change being planned involves automatic vessel cleaning which requires an investment, in our relatively small operations, of over $1 million. Improved ventilation in general will also improve the working atmosphere.

Regarding PVC processing and fabrication, we do not believe that the proposed standard should be written to cover PVC processing workplaces. There is no evidence of medical hazard in these operations.

Although it is possible to detect some vinyl chloride monomer in the processing workplaces, it is unusual to find

any substantial concentrations. Proper workplace ventilation and emphasis on reducing residual vinyl chloride monomer levels in PVC should insure the absence of this risk.

And we're supplying data on the monitoring of processing workplaces within Uniroyal's extensive fabricating facilities, part of which are in this exhibit and part of which will be submitted later. We have additional information currently.

Although we reject the concept of "zero exposure" to vinyl chloride, we recognize and accept our responsibility to protect the health of our workers. We believe that low level exposure to vinyl chloride represents a minimal risk situation. We recommend that a finite "permitted level" be substituted in the permanent standard in place of the "no detectable" requirement.

In our PVC manufacturing operation we feel that we can reduce airborne levels of vinyl chloride to under 50 parts per million as a ceiling limitation. For practical purposes we strongly endorse the concept of a time weighted average value.

In our opinion, the time weighted average number could ultimately be set at 25 parts per million and the ceiling at 40 parts per million if it is felt that sufficient evidence exists to warrant reduction from the 50 parts per million called for in the temporary standard, and we question whether there is any such evidence.

It should be recognized that due to individual plant

sarcoma is increased by any level of exposure, it should be mandatory that we determine first what the incidence of angio sarcoma is in the general population and how it relates to occupational exposure.

Thank you.

JUDGE MYATT: Gentlemen?

DOCTOR LASSITER: I have a couple of questions, to start off with.

One statement that I wanted to ask you about, to make sure I understood it properly -- we only had one copy of your statement to pass around --

You made a statement concerning, I believe the 50 parts per million level, saying that you believed that would be a safe exposure, based on the available evidence?

MR. KLEINFIELD: Yes, sir.

DOCTOR LASSITER: Why do you believe that, based on the findings of the animal studies at 50 parts per million?

MR. KLEINFIELD: I have no confidence -- I don't think we collectively have confidence in those animal studies sufficient to warrant our going to a lower level.

We haven't heard any hard evidence.

DOCTOR LASSITER: So if I understand your position, you would be confident to permit exposure to 50 parts per million for a work force for a working lifetime?

MR. KLEINFIELD: That's a ceiling.

If you would like us to go into a little further detail, Doctor Harris has analyzed considerable data, animal data, human data, and he may want to comment on that.

DOCTOR HARRIS: If you wish, I could, but if you don't think it is necessary, I won't.

MR. KLINE: In your view, what kind of evidence would you need to establish a low level?

MR. KLEINFIELD: The increase of angiosarcoma incidence in the human population associated with vinyl chloride exposure.

MR. KLINE: And in order to acquire a no-detectable level, I assume you would require the same evidence in humans?

MR. KLEINFIELD: I think we would need a stronger indication that something bad is occurring. We recognize some correlation, but we don't see an increasing incidence, and I don't think any of the data show it.

MR. KLINE: Now, if I ask you questions that you covered in your appendices and tables, please forgive me, but it is quite voluminous.

MR. KLEINFIELD: I did skip around; I am sorry.

MR. KLINE: That is all right.

Do you presently perform medical surveillance of your employees exposed to vinyl chloride?

MR. KLEINFIELD: Yes, we do.

MR. KLINE: And for how long have you been performi

this medical surveillance?

MR. KLEINFIELD: I would like to refer that question to Doctor Harris or our Plant Manager.

MR. KLINE: Please do.

DOCTOR HARRIS: Actually, I believe -- is this true, Ben -- that we have had an annual physical examination for our workers in the Paynesville plant for many years.

MR. KLINE: Did that include liver dysfunction tests?

DOCTOR HARRIS: No, I think it did not originally. When NIOSH recommended these in the spring, I think it was, a few months ago, as quickly as we had a chance to get set up for that we did begin such testing.

All of our people have been put through the -- we use the five liver function tests that NIOSH recommended, rather than the SMA 12, that some have used.

We recognize that there is a normal number of abnormalities; that is, in any given test there will be some people above the normal at any one time, and furthermore, these tests are being run on an auto-analyzer, and those are set to give you -- they are set conservatively, so that you get a rather high number.

You see, these aren't run by hand, and so they are set so that you will get a conservative warning, and even so, we have run about 13 percent of the people who had one or more of those functions above the line. Now, as near as we

have been able to find, that is quite a lot lower than some of the others have been reporting, and the experts that we have talked to felt that that was -- was in line.

Now, this will get further attention; we are on the second round, and I believe that nine percent of the second go-around were having abnormalities -- one or more abnormalities. However, we have had no angiosarcoma, no acreosteolysis, prior to the Michigan study, and there hasn't been anything anything showing up so far that we have been able to pick up that is alarming.

And we haven't written it off; it is a continual study.

MR. LEACH: While we haven't run the liver function testing on our people in our annual physicals, our plant doctor has done abdominal palpitation as part of his regular physical for many years, and sort of used this to follow whether there would have been any changes in liver or spleen size through the years, and he has not detected -- well, he has detected in some people changes, but generally this is related to other things.

We have not, in any of the liver function testing that we have done so far, related any of the abdominal palpitation problems detected by our physicians to any of the liver functions tested.

MR. KLINE: Have you had an opportunity to relate

the length of exposure to the abnormalities that you did find?

DOCTOR HARRIS: Yes. Following a meeting a couple of weeks ago, I asked Mr. Leach to have that data drawn together, and he did pull it out and Doctor Forbes and I looked it over and just could not see any evidence of any relationship that seemed to hold up. We tried to tear it apart in various ways.

MR. KLINE: Would you submit that data in a post-hearing comment?

MR. LEACH: Well, this is not by any individual-name records, so --

(Discussion off the record)

MR. LEACH: We could certainly submit it.

MR. KLINE: Thank you. I would appreciate that. Have you made any attempts to follow retired workers?

MR. LEACH: We are including them in the medical surveillance work we are presently doing.

MR. KLINE: Do you have any data presently on that question?

MR. LEACH: It is part of the same body of our current workers. It is part of the body of data we are putting together on our current workers.

MR. KLINE: I see. Does that include deceased

employees also, former employees?

MR. LEACH: Pretty tough to test.

MR.KLINE: Excuse me; I was not referring to testing. I am talking in terms of -- epidemiology.

MR. LEACH: Yes, they are included in the survey that was made of our employees.

MR. KLINE: Would it be fair to say that the basis for wanting to exclude the compounders and fabricators is that the level is not sufficiently high to be unsafe, in your view?

MR.KLEINFIELD: Yes, I think that is consistent with our recommendation. We think whatever level is shown to be unsafe should not be allowed, no matter where it is.

MR. KLINE: On what basis have you concluded that 25 parts per million, as a time-weighted average, would be safe?

MR. KLEINFIELD: Well, we concluded from evidence that we have seen -- hard evidence that we have seen -- that 50 parts per million would be safe.

We know that most people in the industry feel they can go lower; we feel it [illegible] be prudent to go lower. We are attempting to go lower. We think it would be safer than 50 parts per million if there is any danger.

MR. KLINE: I am somewhat confused. If you feel that 50 parts per million is safe, why would you want to go

lower?

MR. KLEINFIELD: Well, first of all, I think -- as I say, it is a matter of prudence. I think there is a certain amount of suspicion, but where the line is between suspicion and knowledge is kind of indefinite here, and I don't discredit the suspicion completely.

I say that if the general feeling is that we should go lower than 50 parts per million, and we probably could accomplish it, we ought to try.

MR. LEACH: We have a problem on these numbers. When we speak of 50, we are talking about a ceiling of 50 parts per million. 25, we are talking about a time-weighted average of 25. They are very different things.

MR. KLINE: I believe a 50 time-weighted average -- well, that is my recollection. Is my recollection incorrect?

MR. KLEINFIELD: I think I referred to 50 parts per million as a ceiling.

MR. KLINE: I heard you referred to it both ways.

DOCTOR HARRIS: I think there was an inconsistency which was probably typographical. I think in the conclusion here, Marty, you did say you feel in good conscience a time-weighted average of 50.

I think that was a slip-up in -- in the forepart he was talking about 25, and it was intentioned to talk 50 ceiling, or else 25 time-weighted average.

Actually, toxicologically, due to the nature of the dosage response, the difference between 25 and 50 is awfully small, though it sounds quite sufficient. If you are down below the level that is likely to have any appreciable incidence, and you go from 25 down to 50, you probably would not be able to tell, epidemiologically, any differences.

That would be my own appraisal of the situation. Even -- I would think even the difference between 50 and 10 isn't very significant. There may be those that would argue that.

MR. KLINE: Were you gentlemen here for Doctor Selikoff's testimony?

MR. LEACH: Yes.

MR. KLINE: I take it that you are of the view that there is the cliff that he was referring to -- that is, the threshold where there is a safe level?

Rather, that was Doctor Schneiderman.

MR. KLEINFELD: I have great respect for Doctor Schneiderman; however, I thik that this gets into conjecture beyond what you have any data for, and I don't know of any study that has ever proven one way or the other whether the calculations are right. They are very interesting: you could doodle to Doomsday.

MR. KLINE: On Exhibit A-6, page 1 of 1, discussing protective clothing, you indicate that the only time impervious

clothing should be required is in extraordinary exposure conditions.

What did you contemplate by that?

MR. KLEINFIELD: Well, I think it would be contemplated, not in the fabrication of things, but in the manufacturing of PVC and vinyl chloride monomer, in the case of spillage, a tank-car or a pipe connection rupturing.

MR. KLINE: I assume that in recent months there have been dramatic reductions in the level of exposure to vinyl chloride; is that a correct assumption on my part?

MR. KLEINFIELD: I don't know if I would call them "dramatic." I think Mr. Leach could address himself to that, because he has actually had the measurements run.

I might mention, though, and I think it is in the same context of your question, that going from a level of, say several hundred parts per million down to 50 parts is one order of magnitude. Going from 50 to 30 is another; going from 30 to zero, we don't think can be attained that easily.

There are several orders of magnitude of difference. That is why I say I wouldn't know if we would call it dramatic or not; we have made changes, and we have reduced it, but that should not be meant to imply that it is going to be very easy, as some previous witnesses have implied, to go from that low level to nothing.

MR. KLINE: Coming back to my question, is it a fair assumption that there have been fairly dramatic reductions in the level of exposure at PVC locations?

MR. LEACH: Yes, I think it is very generally known that most often you don't find something until you start looking for it, and as we began to look for leaks, we found there were some areas where there were leaks from pumps, valves and various things, and obviously we addressed ourselves to correcting those wherever we found them.

MR. KLINE: Have you instituted any new engineering controls in order to reduce levels of exposure?

MR. LEACH: Yes. We made certain changes in operating procedures which were put into effect at once. We also have begun our engineering planning on how we would make engineering changes to our manufacturing operation, to have a lower level of vinyl chloride in the working atmosphere, and our planning to this point has been directed toward engineering the changes in the operations to get us to a level of 10 TWA, because we feel, from our own work and the work of the consulting engineer group which we hired, that it is completely out of the question to attempt to modify a plant more than 25 years old to the new technical level which seems to be advocated by most of the speakers.

MR. KLINE: Have you actually instituted engineering controls in the PVC plants?

MR. LEACH: Well, I don't really know what you mean by "engineering controls;" we changed our method of operation. We have planned for equipment changes which, hopefully, if we have a permitted level to operate at, we will purchase different equipment and install it.

Is that the answer to your question? Perhaps I don't understand.

MR. KLINE: Well, you have answered my next question.

Have you put in new equipment with the aim of having the level of exposure reduced?

MR. LEACH: Yes. Primarily this has been, so far, respiratory equipment.

MR. KLINE: Other than respiratory equipment, have you put any equipment in with the aim of reducing the level of exposure?

MR. LEACH: No.

MR. KLINE: Now, you talked about work practices which you instituted that had the effect of reducing the level of exposure. Would you describe them to us, please, briefly?

MR. LEACH: Yes. We have had a certain level of reactor venting prior to personnel entering the reactor for cleaning, and --

MR. KLINE: Excuse me; is that a change in policy?

MR. LEACH: Well, just a minute; let me finish.

We have had a certain level of ventilation, which was our standard; based on the obvious need to reduce personnel exposure, we have greatly increased the air-flow rate through reactors whenever people are in there.

Also we have increased, or lengthened, the time of sweeping before anybody goes in there. Also, we now require that all those entering the reactor vessels for cleaning wear respiratory protection.

MR. KLINE: Are there any other major work practice that you instituted which have had the effect of reducing overall exposure?

MR. LEACH: We have tried certain things, but I have -- customers have reported to us that certain things we have tried have had an adverse effect on quality.

MR. KLINE: Does that have to do with the recovery of unreactive monomer?

MR. LEACH: No, it does not.

MR. KLINE: Would you tell us some of the things you have tried that have had an effect on the quality of the product?

MR. LEACH: Yes. Increasing the number of batches between vessel cleaning obviously reduces the individual -- the number of times that people must go into the reactors, but as we try this we begin to get quality effects that are

untenable.

MR. KLINE: Is that --

MR. LEACH: That is the major thing that I am thinking of.

The business of removing more monomer from the polymer during manufacture is one where we must install the equipment to do it. This gets into what we are now planning, but we are waiting to see which way the cat is going to jump before we commit the money to it.

MR. KLINE: I am not sure I understand what you mean. Would you explain what you mean, please?

MR. LEACH: Well, equipment installation will be required in order to achieve lower levels of vinyl chloride in the PVC -- stripping or whatever procedure we use to reduce the VC content of our PVC plants, and we have not yet committed ourselves to installation of that equipment until we know what it is that we are going to have to do.

MR. KLINE: I am not sure I understood that, either.

MR. KLEINFIELD: Frankly, I can answer that a little more bluntly.

If the standard comes out that says no detectable level, we will not commit any money to equipment, because we feel it is unfeasible. If we're not going to make it, why spend the money? We will never accomplish it. So we will

shut down.

However, if it comes out at some reasonable level -- perhaps 40 ppm, or something of that nature, and we see we have a chance of getting there, then we can make a commitment.

MR. KLINE: Now, you have indicated that your goal is a ten time-weighted average. When would you expect to be able to reach that goal?

MR. LEACH: By our present scheme of engineering work, we think it would be by the end of 1975.

MR. KLINE: And on what basis have you concluded you could do that?

MR. LEACH: Engineering studies.

MR. KLINE: What engineering equipment and controls do you contemplate to be able to reduce your level to ten parts per million time-weighted average?

MR. LEACH: Well, the result of the monitoring in our plant, which we are doing, indicates where problem areas are. In certain cases, the leaks -- if you would -- can be corrected by tightening up whatever might be causing the leak.

In other cases, it is that the kind of equipment which we have has, by its very nature, a certain amount of leakage; that equipment must be replaced. In this case, we are talking about some of our pumps, some of the compressors, which we use to compress the vinyl chloride gas after it has been moved, back to liquid form so we can handle the vinyl

chloride subsequently in liquid form, increased ventilation -- on and on and on.

We have over the last three months had practically all of our engineering people directed toward finding what the things are that we can do to come up with a program so we have something to talk about each day, and there aren't very many.

MR. KLINE: Are there any other engineering controls that you contemplate instituting which will -- you feel will get you down to the 10 time-weighted average?

MR. LEACH: We don't have the people associated with PVC that Mr. Batone mentioned, but such people as we have assigned to research and development for PVC are all working on this problem, looking for techniques such as either a higher conversion of the polymerization operation or the removal of the unreactive monomer someplace in the process steps.

We are contemplating a lot of things; only when we have done sufficient work will we know which of these has any practical application.

MR. KLINE: Incidentally, I am curious as to why you are trying to get down to ten parts per million time-weighted average if you feel 50 is safe.

MR. LEACH: I didn't say 50 was safe. I am saying 10 is something I think I can reasonably get to with my

have -- in doing any engineering work, you must pick a target that you aim for, an ultimate objective, and if you were to choose 50 parts per million and put in equipment to do that, we would undoubtedly, if the ultimate standard results in 10 or 25, have to replace that equipment. The same equipment would not get to 10 as would get us to 15, so we have chosen, for purposes of our engineering studies, equipment which would get us ultimately to a level of 10, trying to guess what the results of these hearings will get the industry to.

MR. KLINE: Have you studied the question as to whether or not you can get to no detectable level? Have you studied that question?

MR. LEACH: We have considered it, but we have not given it serious study, because in our estimation, it is something beyond our --one: technical capability and, two: financial capability to achieve.

MR. KLINE: Are you suggesting that in effect there is technically feasible equipment which is now available or will soon be available which can get you down to 10 parts per million time-weighted average a year from October?

MR. LEACH: We are addressing ourselves to finding out if we can achieve that. That is the goal we have set; we would also assume, depending upon what the standard results are as the permissible level of exposure, if you would, that respiratory equipment will be available for use by employees

at times when there are excursions above whatever the permissible level might be.

MR. KLINE: I would like to talk for a moment about your automatic vessel cleaning.

Do employees have to enter the vessel after each batch is processed, or on a periodic basis?

MR. LEACH: Employees have to enter vessels, but in some cases it is after each batch, and in some cases after many batches.

MR. KLINE: That would depend on the process that you are using?

MR. LEACH: Yes, and the kind of product we make -- process and product.

MR. KLINE: But the automatic cleaning that you referred to in Text B, page 1 of 1, does reduce the amount of -- the number of times of vessel entry; is that right?

MR. LEACH: Yes. This is something which we are planning to explore, some method for solvent cleaning of reactor vessels which would reduce, if not eliminate, the need to enter vessels for periodic cleaning.

MR. KLINE: Is that a licensed process, or can you execute a license to work that process?

MR. LEACH: We are both studying things from our own imagination and considering things which others feel are feasible, and that they may license to us.

MR. KLINE: I take it that they are licensed. Is that what you are saying?

MR. LEACH: Perhaps they are; but not to us.

We are having some discussions, but we haven't gone further than that.

MR. KLEINFIELD: I think perhaps I can elicit that there are processes available from other manufacturers of PVC, and they might be willing to license us to use them.

We are not convinced that these are applicable to our particular plant; we have our own ideas also.

MR. KLINE: I would like to now discuss, just for a moment, medical examinations.

Are you in favor of or opposed to medical surveillance of employees in fabricating plants?

DOCTOR HARRIS: Well, I think -- I am sure that Doctor Forbes, who is our medical doctor, feels that a good medical program is always wise.

MR. KLINE: I am referring to liver dysfunction tests.

DOCTOR HARRIS: We are not at all convinced. We think that five liver function tests were a reasonable, quick approach on the part of NIOSH. We thought it was constructive and quite laudable; however, we realize that there are so many abnormalities -- there are so many things that could cause a given liver dysfunction in time, and therefore we

plant in Haynesville was over 25 years old, and I understand it has a nameplate capacity of about 140 million pounds per year; is that correct?

MR. KLEINFIELD: That is about correct.

MR. RUSKIN: How does your plant compare in terms of cost efficiency to the newer and larger polyvinyl chloride plants?

MR. KLEINFIELD: I don't understand the relevance of the question to the subject.

MR. RUSKIN: Well, what I am dealing with here is, in terms of cost consideration, and I think it is relevant in terms of economic feasibility.

How does your plant compare in cost efficiency to the newer and larger PVC plants?

MR. KLEINFIELD: I suspect it is at a disadvantage. Most old plants are at a disadvantage, any fabricating or PVC manufacturing plant is likely to be at a disadvantage, just as a general rule of thumb.

MR. RUSKIN: Well, is there a recognition in the industry that some of the older or smaller polyvinyl chloride plants are generally less efficient or are becoming obsolete?

MR. KLEINFIELD: I think that is a fair statement.

MR. RUSKIN: So the state of the technology within polyvinyl chloride plants, plant design and so forth, has changed considerably over that 25-year period?

MR. KLEINFIELD: Well, I think they have changed in terms of size of reactors, for example -- newer plants and much larger reactors which produce more material and occasion less entry into the reactors to clean them for a certain number of pounds of production, the lower labor content in the operation.

MR. RUSKIN: And these would all affect the cost efficiency of those plants?

MR. KLEINFIELD: I suspect they must.

MR. RUSKIN: You have stated that you were formerly involved in a joint venture with the Mar-Chem operation --

MR. KLEINFIELD: We are currently.

MR. RUSKIN: In the production of vinylchloride monomer for the acetylene process?

MR. KLEINFIELD: That is correct.

MR. RUSKIN: Are you still producing vinylcholoride monomer through the acetylene process?

MR. KLEINFIELD: Yes.

MR. RUSKIN: A number of plants have phased out their acetylene operations because they were no longer cost-competitive. Are you finding a problem in terms of the production -- acetylene production of the monomer -- that there is a similar problem?

MR. KLEINFIELD: I don't think we are quite in that position. I think we compare probably more favorably than

most people in the industry using the same process.

MR. RUSKIN: If your acetylene operation were to shut down, would that have any effect on your overall chemical operations, sales and profits, your general viability?

MR. KLEINFIELD: It would shut us down completely as a PVC manufacturer and as a fabricator.

MR. RUSKIN: Is that based on assumptions that you believe you would be unable to obtain any other monomer source?

MR. KLEINFIELD: Yes. It is in short supply now, and as we foresee, it will be in short supply for the next several years.

MR. RUSKIN: You have mentioned, as well, the great demand for polyvinyl chloride for 1980.

Is it accurate to say that this demand provides the market conditions under which a profit is readily attainable to justify new investments in plants and equipment?

MR. KLEINFIELD: Well, that is a fairly difficult question to answer, because if we view the past economics of the PVC industry, go back just a few years, everybody was losing money on it -- I say that as a general statement, and I would get agreement on it from manufacturers -- and the demand was going up by leaps and bounds and so was the capacity, and the competitive situation was such that nobody was making any money on it, and I expect we will get into the same sort of thing.

And I think if our costs go up fast to attain the capacity to supply this demand, and everybody is looking for the same 50 percent share of the market, we will be back in that same hole again.

So I don't think it is a profit-making situation that we are looking at.

MR. RUSKIN: Well, is there currently an over-capacity of polyvinyl chloride in this country?

MR. KLEINFIELD: Oh, no; there is a tremendous shortage.

MR. RUSKIN: Of polyvinyl chloride capacity?

MR. KLEINFIELD: Right.

MR. RUSKIN: So with the great demand for polyvinyl chloride resins and so forth, do there exist currently and expected over the next few years, market conditions such that there would be enough return to justify new plants or new investments in polyvinyl chloride field?

MR. KLEINFIELD: I think a number of manufacturers are looking at it that way, and they have announced expansion plans, and as I mentioned before, I think they are all looking at the same 50 percent share of the market.

And there are -- you know, ten or twenty manufacturers, and it isn't going to work out that way.

MR RUSKIN: Well, finally, if I might be more specific on this, Chemical Week reported, for May 10th, 1972,

refers to a prominent PVC executive who stated that a 200 million pounds per year grassroots PVC facility would cost $24 million. The nominal return on investment would require a profit of about two cents per pound.

My question is: with -- would the extent of current and future demand, and the increase in prices which PVC is getting on the open market, can this two cents per pound -- or whatever the figure might be currently -- be obtained in the market, justifying new plants -- the construction of new plants in the polyvinyl chloride area?

MR. KLEINFIELD: I don't know if I can really answer that question.

Certainly for ourselves, I don't think two cents would be enough, to justify replacement of all our equipment.

MR. RUSKIN: Well, my question is, just basically, if a firm were considering to build a new plant --

MR. KLEINFIELD: I am not going to try to answer for the industry.

MR. RUSKIN: Well, if you were looking -- based on your experience with the market in polyvinyl chloride, would the market conditions support the building of a new facility? Could you obtain, upon the selling of a pound of polyvinyl chloride, enough profit to justify investments in plant and equipment?

MR. KLEINFIELD: Excuse me.

(Discussion off the record)

MR. KLEINFIELD: I am afraid I couldn't answer that competently. We don't know at this point -- if the proposed permanent standard is forced upon us, we don't know what it will cost to build a new plant.

MR. LEACH: Well, 1972 estimates have nothing to do with what we would be required to do in 1975.

MR. RUSKIN: I understand that. I just --

JUDGE MYATT: I am going to cut you off from this line of questioning. Obviously they can't give you the answers.

Now, do you have something else to ask?

MR. RUSKIN: No, that is my last question.

MR. HECKMAN: Jerome H. Heckman, SPI General Counsel. I just have two questions for Mr. Kleinfield, if I may.

You heard the OCAW testimony earlier when there was considerable discussion about this 11 parts per million average at the Goodyear plant, and I just wanted to inquire of you whether or not your support of the 25 ppm TWA concept really is approximately consistent with that achievement, in light of the way in which they calculated that 11 parts per million, as an average?

MR. KLEINFIELD: I am not sure how they came up with that number.

MR. HECKMAN: Well, they said that they have higher excursions, and that the 11 was an average.

What I want to know is whether your 25 ppm-TWA concept is approximately consistent with that achievement, or better?

MR. KLEINFIELD: I would say yes, approximately, within the limits that Doctor Harris described before. He doesn't distinguish, really, between such differences. The data certainly don't.

DOCTOR HARRIS: I didn't hear that testimony. Is that an average of all their plants?

MR. HECKMAN: I had a little trouble figuring that outmyself, to be honest with you, so I -- no; it was just Niagara Falls. That part I remember.

DOCTOR HARRIS: I would think that our data is not too terribly different. There are some hot-spots that we don't know how to get down as low as we would like, and that pulls the average up, you see. And some are talking in terms of, well, in those cases we wear respirators, so those are not included, and if we exclude those areas then that pulls our average down, and it wouldn't really be very different.

But I am not sure what theirs were figured on.

MR. HECKMAN: Your goal, the goal that you have been talking about, so that the record will be clear on this, is 10 parts per million TWA, is it not?

MR. LEACH: That is right. That is what we are designing our engineering improvements to achieve.

MR. HECKMAN: Does it follow that because you can get down to 25 or 10 ppm-TWA, that ultimately you could achieve a no-detectable level?

MR. LEACH: I would think not,, because we are talking about an asymptotic approach to a line here, and it gets more difficult with each step.

MR. HECKMAN: So it is your opinion, is it not, that you could not achieve a non-detectable level?

MR. KLEINFIELD: That is what we said.

MR. HECKMAN: Thank you very much.

JUDGE MYATT: Yes, sir?

MR. TOPOL: Allen Topol, from Covington and Burling representing Tenneco Chemicals.

You testified in colloquy with Mr. Clark, I think, about the possibility of getting --

MR. KLEINFIELD: I'm sorry; were you addressing that to me?

MR. TOPOL: Yes, I am.

I think in the colloquy with Mr. Clark a while ago, you were asked about the possibility of getting equipment faster on a rush order basis than the normal equipment shipment time.

How many polyvinyl manufacturers are there in

country?

MR. KLEINFIELD: I think there are 23 or 24.

MR. TOPOL: How many plants is that?

MR. KLEINFIELD: 36 locations, I think.

MR. TOPOL: If you had everyone in the industry ordering similar equipment at the same time, what would happen to your assessment about whether you could get the equipment on an accelerated basis?

MR. KLEINFIELD: My assessment was -- I don't know whether this came across -- that we were not going to have much luck, but under those conditions that you describe, we would have to compete for the equipment, and I don't know how we would make it.

MR. TOPOL: And that would slow the time down for everyone?

MR. KLEINFIELD: Certainly.

JUDGE MYATT: Yes?

MR. CONNOLLY: Following Mr. Topol's question, I assume you couldn't answer the question Mr. Clark raised unless you knew, for instance, what kind of work practices the corporation we're dealing with was going to supply the equipment was involved in.

By that I mean if they were working three shifts full time now, they obviously couldn't put anymore people on or increase their capacity at that time.

So you would have to know that type of information before you could decide whether or not a process could be speeded up.

MR. KLEINFELD: That is a fair statement, sir.

MR. CONNOLLY: Another question.

A number of corporations have testified today that the figure of ten parts per million time weighted average calls for a target that they're trying to get to.

Is your testimony ten parts per million time weighted average also a target and a goal that your corporation is trying to get to by the end of 1975?

MR. KLIENFELD: Yes, as Mr. Leach mentioned, that this is a goal that we set up and we said that we don't believe it is feasible to reach zero. We are going to try to reach ten if it is forced upon us.

MR. CONNOLLY: You don't have any idea whether or not

in fact you can reach that by the end of 1975?

MR. KLIENFELD: Right now I would say that the chances are less than 50/50 that we will reach it. We are simply trying.

MR. CONNOLLY: You are setting up another target then and you are hoping that you are going to get to it?

MR. KLIENFELD: Yes.

MR. CONNOLLY: All right.

That is all.

Thank you very much.

JUDGE MYATT: Anyone else?

(No response.)

JUDGE MYATT: Gentlemen, please step down.

U-Brand Corporation?

Is there a representative here?

(No response.)

JUDGE MYATT: All right.

General Dynamics Corporation?

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